

GMC 822

Understanding stakeholder perspectives on the GMC's quality assurance of medical education and training

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Ann Griffin

Paul Crampton

Leila Mehdizadeh

Michael Page

Laura Knight

Antonia Rich

Rowena Viney



Executive Summary

Background, aims, objectives

The General Medical Council (GMC) hold a crucial role in quality assuring medical education and training in the UK and is currently reviewing its approach. This research provides an in-depth and systematic evaluation of how the GMC currently undertakes this role and considers future directions. The aim was to synthesise a wide range of perspectives from key stakeholders about the GMC's quality assurance processes. Our objectives were to synthesise their perceptions of: 1) strengths and weaknesses of the GMC's Quality Assurance Framework (QAF), 2) suggestions for improvement, 3) assuring quality of standards in equality and diversity, 4) proportionality in the current approach, 5) collaboration with others and 6) alignment with best practice.

Methods

A qualitative methodology employed interviews to explore a diverse range of stakeholders' views about the impact and effectiveness of GMC's QAF. We used realist evaluation to develop a deeper appreciation of how and why the components (standards, monitoring, visiting, etc.) of the GMC's QAF are effective, or not. The research included: a rapid review of the quality assurance literature from 2012 onwards; interviews with stakeholders; and six case studies.

Aligned to the recruitment strategy the sample was professionally diverse and represented a wide range of national and international stakeholders within and outside medicine. In total we conducted interviews with 36 individuals representing 34 organisations, producing a considerable quantity of original data: 35 hours, 27 minutes. The individuals interviewed were senior personnel such as directors, chief executives, managing directors, accreditation leads, and education/standards/quality assurance managers.

Results

Overall there was recognition that the GMC has robust practices in quality assuring medical education and training. The GMC's QAF was commended by stakeholders for being comprehensive and for enabling a broad understanding of an organisation's performance. Quality assurance partners (QAPs) were able to offer specific critical insights into how the GMC's quality assurance (QA) processes actually impacted on their organisations. Whereas non-quality assurance partners (non-QAPs) reflected on the GMC's QA processes by comparing them with that of their own organisations/profession, and trends in QA more broadly.

The GMC's approach to quality assuring medical education and training was largely considered proportionate to the risks involved, although QAPs were more likely to be critical of how effective and proportionate the QAF is compared to non-QAPs. The main weaknesses identified fell broadly into two themes, those related to the overlap between QA bodies and those related to a heavily data driven approach associated with the GMCs monitoring activities. In order to reduce overlap, there was a unanimous view that collaborating with other QA bodies made sense, but a number of significant practical challenges to doing so were identified.

In terms of future developments, all stakeholders had limited insights in relation to quality assuring fairness, and often struggled to provide a coherent answer to how equality was integral to quality assurance. A balance favouring enhancement over accountability approaches was advocated and

was felt to be in keeping with current global trends in assurance. There was limited evidence from the literature to advance understandings. It was believed that closer partnership working was important in delivering enhancement, and case study data demonstrated how partnerships can be enhanced through collaborative practices.

Conclusions

Effective working relationships foster trust and informal communication channels allow the early communication of emerging risks and support quality enhancement approaches. Enhancement-oriented approaches should also facilitate closer partnership working, as enhancement is typically seen as more positive than assessment-oriented assurance approaches. Openness between the provider and the GMC can help to bridge the gap from policy into practice. In acknowledging the GMC's responsibility to ensure minimum standards are met, a hybrid model of cyclical plus risk-based visiting may help to build provider relationships and drive improvement while also ensuring minimum standards. The move towards a risk-based approach is in keeping with current trends in regulation globally, but accurately and reliably gauging risk is reported to be challenging. Risk is context-dependent and it may need to be defined differently across undergraduate and postgraduate medical organisations. Greater clarity on the relevance of data requests and providing timely constructive feedback on submissions should prevent stakeholders' disengagement in monitoring and self-assessment practices.

The implications of the findings on equality and diversity point towards making fairness more explicit within quality assurance activities and having action points that directly relate to equality. For the GMC to tackle issues such as differential attainment, widening participation, and equality within training environments it should be much clearer how the GMC will regulate these particular aspects in practice.

In addressing regulatory overlap by exploring collective assurance, there is a need for a comprehensive review and further consultations in order to understand if the benefits would outweigh costs. There are many theoretical advantages, and stakeholders were overwhelmingly positive about streamlining these processes, but there are significant challenges in practice. A clear stance on organisational remit, and particularly boundaries, is anticipated to be a key mechanism in conducting effective joint quality assurance.

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1. Introduction

The GMC holds a crucial role in quality assuring medical education and training in the UK. This report provides an in-depth and systematic evaluation about how the GMC currently undertakes this role. A qualitative methodology, using realist evaluation, explored a diverse range of stakeholders' views about the effect and effectiveness of GMC's quality assurance framework (QAF). Stakeholders included those regulated and closely involved with the QAF, i.e. the GMC's quality assurance partners (QAPs); as well as regulators from other organisations both inside healthcare and outside, including international organisations, labelled in this report as non-quality assurance partners (non-QAP). We used a realist position to develop a deeper appreciation of how and why the components (standards, monitoring, visiting, etc.) of the GMC's QAF are effective, or not. This research includes a (1) rapid synthesis of the quality assurance literature from 2012 onwards; (2) interviews with 36 stakeholders and (3) case studies.

1.1 Aims and research questions

The aim of this research was to gather, interpret and synthesise key stakeholder perspectives about how the GMC currently undertakes their role of quality assuring medical education and training in the UK.

Research questions

1. What are the strengths and weaknesses of the GMC's quality assurance framework?
2. What areas, if any, do stakeholders view as problematic?
3. What suggestions, if any, do stakeholders have for improvement?
4. What are stakeholder's views on the quality assurance of standards for equality and diversity?
5. How effective and proportionate is the approach to quality assurance?
6. Would collaboration with other professional bodies/ system regulators improve effectiveness and proportionality?
7. How does the GMC's approach align with current best practice in quality assurance?
 - a. How does the GMC's approach compare and contrast to other selected national and international established practices within healthcare?
 - b. How does the GMC's approach compare and contrast to other selected national and international established practices external to healthcare?
8. Taking into account stakeholder perspectives on the GMC's approach, what are the implications of the findings?

The GMCs QAF is a multi-faceted approach including: setting standards, approving education settings, monitoring activities including self-assessment and enhanced monitoring, visits, sharing evidence and identifying good practice. At the core of the QAF is patient safety and embedded in all the components is fairness (see figure 1). Each of these components plays an important role in quality assuring medical education and training and so are evaluated in detail in this report. Furthermore, during this research key trends in quality assurance were actively explored to provide

insights about quality assurance in other contexts and provide exemplars of advancements in the field.

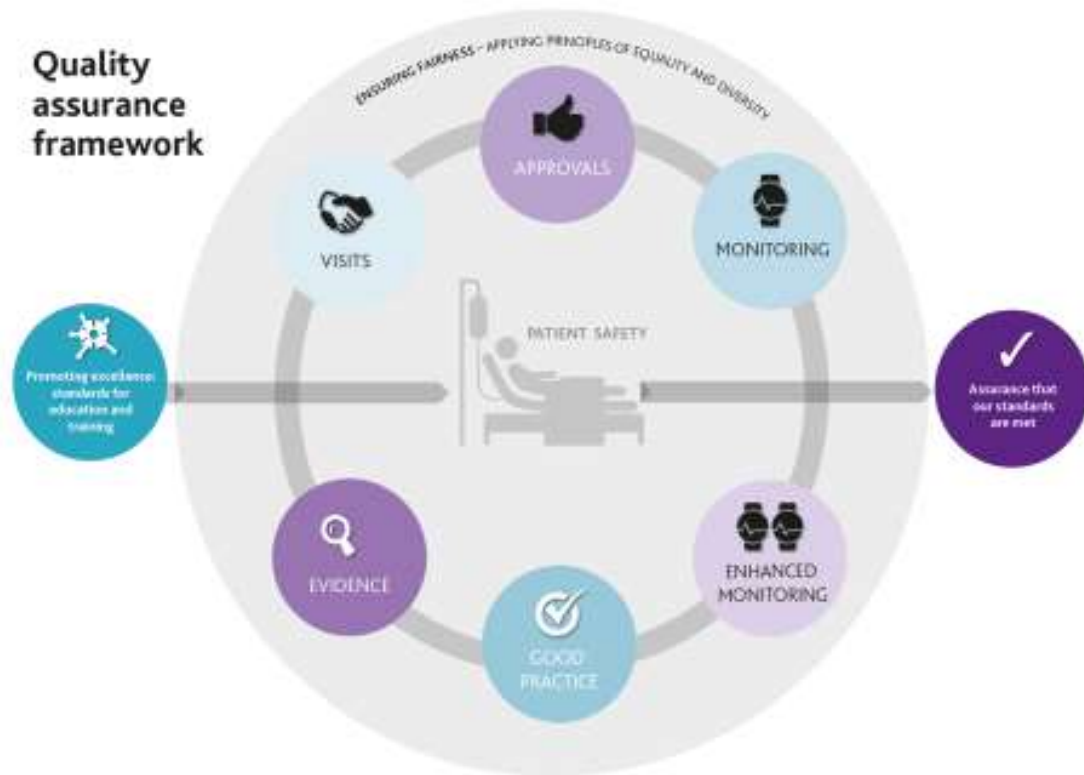


Figure 1: The GMC's Quality Assurance Framework

1.2 Methodological approach

Quality assurance activities designed by regulatory bodies take place within varied and complex social environments; for this reason, the same intervention can impact on individuals, teams and organisations in different ways. Although there are intended consequences explicit in the design of the GMC's QAF, such as meeting standards, there are also implicit drivers which are triggered when the intervention is applied in certain contexts. Complex interventions, like the translation of quality assurance (QA) policy into practice, require a fine-grained research approach to exploit the ways in which the intervention may (or may not) lead to certain outcomes in certain situations. Realist evaluation incorporates a focus on four theoretically constructed and inter-related core questions: what works, for whom, in what circumstances, and how (Pawson *et al.*, 2005; Pawson, 2013), enabling a deeper appreciation of how components of the GMC's QAF are effective; offering an assessment of *whether* it works or not, as well as why this is so. We explored the complex links between contexts (where, when and with whom the intervention takes place), interventions (activities applied to assure quality), mechanisms (underlying processes for why the intervention is/is not effective), and outcomes (intended and unintended consequences) and outline how similar interventions may be affected by different contexts, leading to different outcomes (Wong *et al.*,

2012). Case studies are illustrative of this approach. We explored how the activities of the QAF may support or undermine quality advancement for different organisations, and at different times.

2. Methods

2.1 Design

We used three approaches including:

- Rapid literature review
- Qualitative interviews with key stakeholders
- Case study analysis

2.2 Qualitative Interviews

Qualitative data was gathered by interviews principally via telephone or skype.

This study was registered with UCL's data protection office on 06/06/18 and approved by UCL ethics on 15/06/18, project ID: 6281/003.

2.3 Interview schedules

A semi-structured interview schedule ensured a common set of interview questions while leaving flexibility for stakeholders to respond. Two interview schedules were designed (see appendices), one tailored for the GMC's QAPs who had direct experience of the GMC's QAF and another for those non-QAPs. Interview schedules explored each of the components of the GMC's QAF and explored current issues pertinent to the field of QA. The interview schedule for QAPs piloted with three researchers present ensuring appropriateness of questioning and researcher standardisation.

2.4 Sampling frame

We aimed to have 45% representation from group A) health sector: medical (UK) and 55% from other organisations including: B) health sector: non-medical (UK); C) health sector: medical (International); D) non-healthcare education (UK); E) non-healthcare education (International); and F) other professional regulators.

Group A consists of the GMC's QAPs - medical schools, Deaneries and Royal Colleges in the UK - and we aimed to recruit an even split between undergraduate and postgraduate medical education organisations. Group A also included other medical stakeholder representatives and systems regulators.

Groups B – F reflect non-partner organisations with a quality assurance function within and outside of the healthcare context.

Projected sampling included representation from all four of the UK regions, European countries and the rest of the world.

2.5 Recruitment

To facilitate recruitment of stakeholders and to provide a detailed briefing about the GMC's QAF, a 15 minute video was produced. It provided a consistent interactive way of informing stakeholders about the full breadth of the GMC's quality remit. The video and script were provided to stakeholders prior to participation.

E-mail invitations were sent to stakeholders with information sheets and consent forms. Non-responders were sent two reminders.

2.6 Procedure and data analysis

Interviews were conducted one-to-one with stakeholder organisations. These were audio-recorded and transcribed verbatim. We developed an analytic coding framework that we consistently applied to each transcript to ensure all data was analysed. Our coding and interpretive phase of analysis reflected a realist approach as we identified contexts, mechanisms and outcomes in the data set.

2.7 Case studies

Realist approaches often include specific examples of where particular interventions have been demonstrated to be successful (or not) in certain contexts. We therefore sought to identify and report illustrative case studies across the stakeholder group to help the GMC advance their understandings on complex areas and to:

- 1) Understand how the QAF translates into real world applications;
- 2) Elaborate on mechanisms (barriers and facilitators) identified or not well evidenced in the literature, or identify new contexts or mechanisms not previously identified in the literature; and
- 3) Describe and illustrate in further detail how mechanisms operate, and in what context activities assure quality.

The case studies primarily drew on the interview data and were substantiated with secondary data where relevant (e.g. reports, publications, presentations).

3. Results

3.1 Rapid literature review

Our initial searches returned 1067 hits, however, after screening only 12 articles met the inclusion criteria. Research into quality assurance is sparse and tends to come from the field of education rather than medical education. The literature review on the impact of visits was the most frequently researched area (seven papers), with other aspects being subject to less research (approvals, two papers; enhancement, two papers; best practice, one paper). All these studies are summarised below.

Visits: According to research undertaken by Forrest (2015), the role of visits in driving improvement depends on two things, the approach taken to inspection and the current performance of the organisation. Drawing on case study evidence from three further education colleges in England, Forrest (*ibid.*) described the impact of Ofsted inspectors as taking a new, collaborative approach to inspection in all three colleges, which represented a change from the more traditional top-down accountability-oriented approach. This collaborative approach, in which challenge was balanced with support, resulted in Ofsted inspectors and institutions experiencing a degree of “co-ownership” of improvement (p. 296). Inspectors engaged in constructive dialogue with the principals and senior staff about the context of each organisation and how, from their perspective, the efforts at improvement were going. The new approach was reported as being valued by the principals. The author noted that in two of the three institutions, inspection against published criteria was associated with improvement – in both cases, the principals had responded to previous “satisfactory” (as opposed to “good” or “outstanding”) inspection judgements by pursuing improvement agenda that were aligned with, although not necessarily confined to, the components of Ofsted’s Common Inspection Framework (CIF). In the third – an underperforming college – it appeared that the imposition of frequent inspection visits and a two year window within which to move their institution from “satisfactory” to ‘good’, caused the senior leaders to narrow their focus on meeting threshold inspection standards and avoid the risks associated with innovation. The principal also found that the risks associated with failing to meet the required standard distracted them from other non-CIF priorities, such as managing finances and restructuring the organisation.

Altrichter and Kemethofer (2015, p.32) report a phenomenon called “accountability pressure” associated with visits. The authors define accountability pressure as “pressure on individual schools and their representatives to act in conformity with the standards of an accountability system and to take action to improve school quality and effectiveness” (p. 37). Accountability pressure on school principals led to their greater attention on standards, stakeholders’ perceptions of inspection findings, and being more actively involved in improvement activity. However, unintended consequences were also revealed. These included narrowing down the curriculum offered, discouraging innovation and negatively impacting on staff morale. Recent work undertaken by Jones *et al.* (2017) established the existence of similar unintended effects across seven European countries, including the UK. Furthermore, Creemers and Kyriakides (2012) found that the application of regulatory pressure alone failed to generate improvement in struggling institutions.

It should be noted that accountability pressure in Altrichter and Kemethofer's (*ibid.*) study did not accrue purely from visits, but was deemed to be associated with consequential regulatory activities such as reporting and sanctions. The authors note that the public rating of institutions according to "threshold levels" (p. 39) (such as "outstanding," "satisfactory" or "inadequate") was also likely to generate accountability pressure. They also identified that the approach taken to visits impacted on accountability pressure. They proposed that "differentiated" or risk-based visits (p. 39) (i.e. non-cyclical visits which were linked to triggers or concerns) are likely to generate more pressure than planned or "cyclical" visits. In support of a differentiated approach to visits, Ehren *et al.* (2015) large scale study of schools across Europe (n=2239) found that, if conducted in addition to cyclical visits, a differentiated approach which looked at educational practices and outcomes, and in which the results were made publicly available, was more effective than cyclical visits alone.

In exploring empirically the mechanisms of action of school inspections, Jones and Tymms' (2014) realist evaluation found that regulatory activities associated with improvement included: setting standards; the provision of feedback; employing a system of sanctions and rewards; monitoring schools by the collection of information; and public accountability. Griffin *et al.* (2017) also found that visits were associated with quality improvement, by driving self-assessment and internal quality review, as long as certain conditions were met. These included the visiting team having relevant expertise, diversity of team membership, facilitation of knowledge transfer between institutions and the provision of timely feedback.

Reports and approvals: An analysis of accreditation reports for pharmacy education programmes in Ireland (de Paor, 2016) suggested a positive association between external accreditation and quality. The reports that were analysed had been made publicly available by the Pharmacy Society of Ireland (PSI) and had been produced after panel deliberations that comprised the PSI's ongoing approval of three pharmacy schools in Irish universities. The reports contained information on the panel's decisions against nine standards and appeared to drive improvements by issuing recommendations. Thus, the reports revealed the views of the professional accrediting body as a highly influential stakeholder and highlighted areas for further development. Moreover, de Paor (2016) notes that as well as recording panel judgements against standards, the reports drew attention to the professionalism of individual staff members. De Paor perceives that the reports therefore spoke to two parallel concepts. On one hand, he argues, traditional approaches to quality assurance follow an "accountability logic" (p. 238), which is defined as a concept of quality assurance that "obliges higher education institutions to adhere to, and be accountable against, standards of quality and other regulations" (p. 233). On the other hand, de Paor describes a professional responsibility logic: "a concept [of quality assurance] that to a larger degree relies on professional integrity and values in dynamic interplay with the standards of his/her profession" (Solbrekke & Sugrue, 2013). The latter concept, the author argues, is likely to empower individuals to take responsibility for enhancement as well as meeting regulatory standards, but no empirical evidence was offered to support this claim.

Blouin *et al.* (2018) also identify an assurance/improvement duality of purpose underpinning accreditation. Their interview study, undertaken with deans and faculty leaders at 13 of Canada's 17 medical schools, revealed that accreditation was associated with establishment of additional internal processes likely to be associated with quality improvement in medical education. These processes included: data collection and analysis; monitoring; the creation of policies and procedures; and continuous quality improvement. However, the authors also identified negative consequences of

accreditation, including cost, low staff morale, threats to school reputation and the suppression of innovation through a focus on adhering to standards.

Assurance versus enhancement: A number of the articles discussed thus far have broached the issue of assurance versus enhancement with the general consensus being that while it is desirable that regulators should be able to encourage both, effective assurance activity is often associated with suppressing innovation. In Lang's (2015) consideration of the tensions between these two activities in the quality assurance of medical schools in the province of Toronto, he concludes that the two activities "are fundamentally different in terms of process" (p. 216). For example, benchmarking and measurement against standards tends to produce institutional isomorphism, whereas innovation tends to give rise to heterogeneity. Lang (*ibid.*) proposes "self-regulation with rules" as an approach to finding the balance between driving assurance and improvement at policy level.

At heart, Lang's (2015) proposals amount to self-assessment against published standards, which was a concept explored by Tackett *et al.* (2016). They note that while institutional self-assessments can drive quality improvement, they are challenging to conduct, and standards may need to be revised in order to be effectively operationalised for self-assessment. Furthermore, doubts have been raised about the validity and reliability of institutional self-assessment – a number of principals who participated in Jones *et al.* (2017) Europe-wide study of quality assurance in schools admitted to misrepresenting their institution in reports sent to the inspectorate.

Collaborative approaches: The report by Ehren *et al.* (2014) on international approaches to quality assurance in school-based education highlighted a greater role for collaboration in driving up standards. Examples included encouraging schools to work together in local clusters to improve sharing of best practice, as well as providing a role for stakeholders in creating and developing standards. The authors suggest that inspection criteria might include "standards for effective collaboration between schools" (p. 6) and suggest that inspection should involve visiting all of the institutions in a cluster at the same time. While they cite examples from the UK and Europe of cluster-based improvement initiatives, the authors conclude that evidence regarding effectiveness is currently lacking.

3.2 Interviews and case studies findings

3.2.1 Stakeholder sample characteristics, context

In total we conducted interviews with 36 individuals representing 34 organisations (see table 1), producing a considerable amount of original data: 35 hours, 27 minutes. Interview duration ranged between 48-88 minutes with a mean length of 63 minutes. Four researchers (AG, PC, LM, MP) conducted the interviews in June-August 2018.

Aligned to the recruitment strategy the sample was professionally diverse and represented a wide range of national and international stakeholders within and outside medicine (see figure 2). There were 12 QAPs and 22 non-QAPs, with 27 (79%) of these from the UK and 7 (21%) international. For the QAPs all four nations were well represented (see figure 3). See figure 4 for international stakeholders. Organisations will not be named to protect anonymity.

A wide range of professions were represented (see table 1) including QAPs (undergraduate/postgraduate/Royal Colleges; n= 12, 35%), healthcare medicine (n=11, 32%), education (n=5, 15%), health professions non-medicine (n=4, 12%) and other professions (n=2, 6%). The individuals were often senior personnel such as organisation directors, chief executives, managing directors, accreditation leads, and education/standards/quality assurance managers.

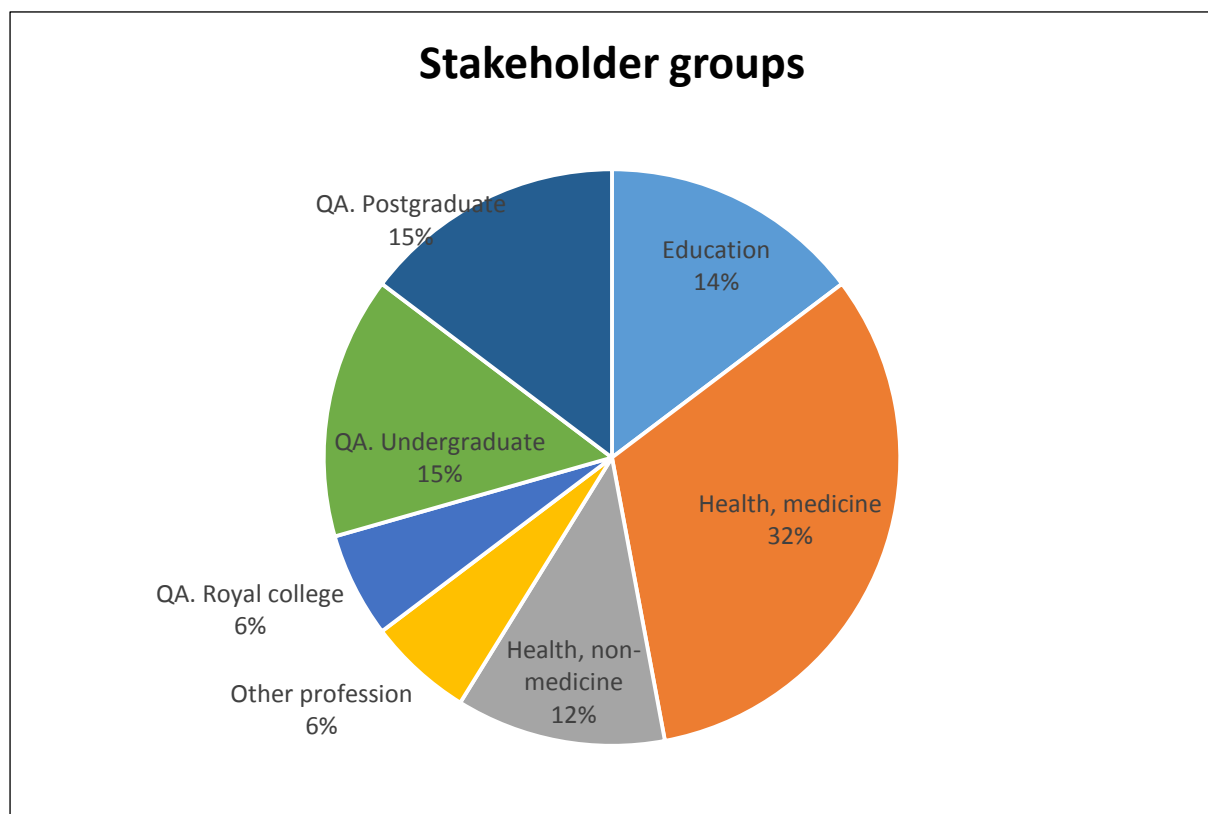


Figure 2: Breakdown of stakeholder organisational demographics

Table 1: Demographic information of the organisations represented

Key: QA=Quality Assurance partner, Health=health organisation, Med=medicine organisation, UG=undergraduate, PG=postgraduate, RC=royal college, INT=international based, UK=United Kingdom based

Interview number	ID	QA partner (Y/N)	Profession Sector	Location (coverage)
1	HealthMedINT1	N	Health, medicine	International
2	QAUG2	Y	Undergrad	UK
3	QARC3	Y	Royal College	UK
4	OtherprofessionUK4	N	Other Profession	UK
5	QAUG5	Y	Undergrad	UK
6	HealthMedUK6	N	Health, medicine	UK
7	HealthMedUK7	N	Health, medicine	UK
8	EducationUK8	N	Education	UK
9	HealthNon-MedUK9	N	Health, non-medicine	UK
10	QAPG10	Y	Postgrad	UK
11	HealthNon-MedINT11	N	Health, non-medicine	International
12	QAPG12	Y	Postgrad	UK
13	HealthMedINT13	N	Health, medicine	International
14	QAPG14	N	Health, medicine	UK
15	QAUG15	Y	Undergrad	UK
16	QAPG16	Y	Postgrad	UK
17	EducationUK17	N	Education	UK
18	HealthNon-MedUK18	N	Health, non-medicine	UK
19	QAUG19	Y	Undergrad	UK
20	HealthMedINT20	N	Health, medicine	International
21	HealthMedUK21	N	Health, medicine	UK
22	OtherprofessionUK22	N	Other profession	UK
23	HealthMedUK23	N	Health, medicine	UK
24	QARC24	Y	Royal College	UK
25	EducationUK25	N	Education	UK
26	HealthMedUK26	N	Health, medicine	UK
27	HealthNon-MedUK27	N	Health, non-medicine	UK
28	QAPG28	Y	Postgrad	UK
29	QAUG29	Y	Undergrad	UK
30	HealthMedINT30	N	Health, medicine	International
31	EducationUK31	N	Education	UK
32	EducationINT32	N	Education	International
33	QAPG33	Y	Postgrad	UK
34	HealthMedINT34	N	Health, medicine	International

QA partners coverage

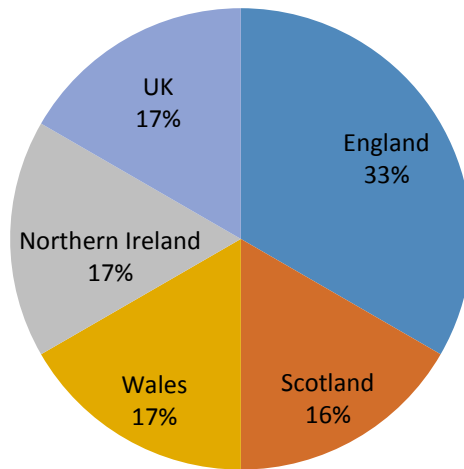


Figure 3: Breakdown of QAP's by geographical areas they represent

International stakeholders

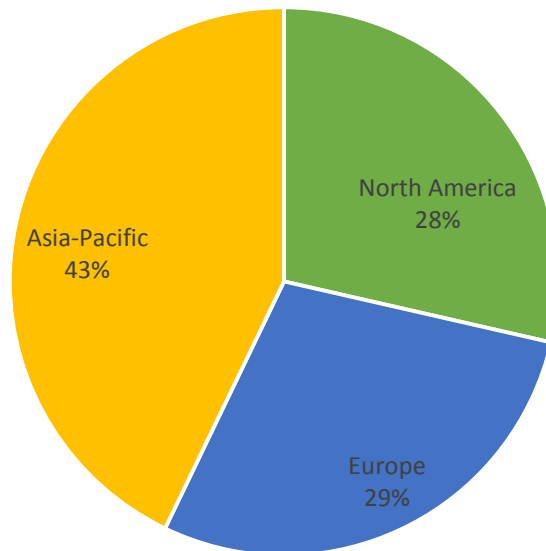


Figure 4: Breakdown of Non-QAP's by geographical area they are based

3.2.2 Results

This section presents stakeholder interview data and is organised into three themes. Theme 1 describes stakeholders' overall perceptions about the GMC's QAF; Theme 2 reports stakeholders' views on the effectiveness of the specific components of the GMC's; and Theme 3 details stakeholders' suggestions for improvement. In keeping with a realist approach this research highlights examples what works, for whom and in what circumstances. Case studies are used to exemplify contextual factors, mechanisms of action and outcomes, both positive and negative, and are presented in Theme 2 which examines the specific components of the GMC's QAF. Also embedded in the themes described in figure 5 is the comparative analysis. Comparisons are drawn throughout the analysis and contrast three main stakeholder groups: the QAPs and the non-QAPs; other national and international healthcare regulators; and other national and international regulators external to healthcare.

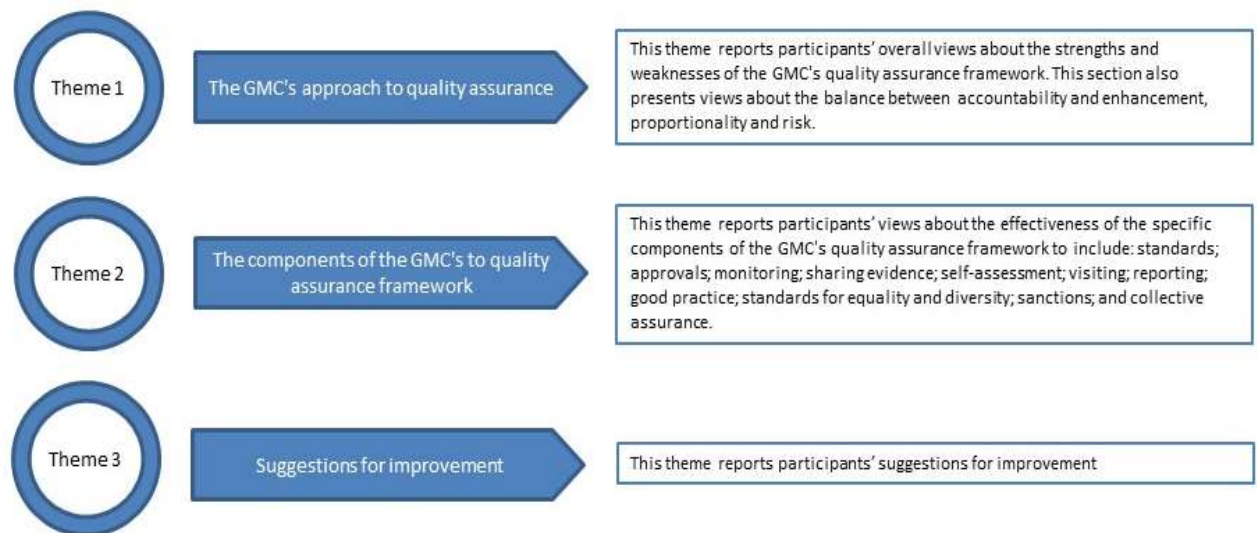


Figure 5: Themes

3.2.3 Theme 1: the GMC's approach to quality assurance

Theme one explores stakeholders' overall perceptions about the 1) strengths and 2) weaknesses of the GMC's QAF. It also examines stakeholders' views about 3) the appropriate balance between accountability and enhancement, proportionality and risk in quality assuring medical education and training, including developments for triangulating or predicting risk.

Strengths

Four key strengths were identified: the comprehensiveness of the framework; the influence of the GMC; the national training survey (NTS) and relationships.

The overall **comprehensiveness of the QAF** was discussed as a key strength; the overarching structure was regarded as holistic, rigorous, logical, integrated and proportionate - a "universal evaluation system" (EducationUK31), providing national standards and recognising both risk and good practice. All stakeholders reported assurance in the multiple components of the QAF, which combined contributed to a broad understanding of an organisation's performance and therefore the

overall effectiveness of the QAF. The QAF was reported as outcome-focused and “recognisable” in both structure and language by other healthcare and non-healthcare stakeholders, nationally and internationally. QAPs appreciated the clarity of the QAF and the three-tier model which when the model was adhered to worked well, allowing QAPs to work effectively having clarity about their roles and boundaries.

The influence of the GMC: The GMC was noted to be at the forefront of quality assurance in medical education and training nationally and internationally: “I believe a lot of national and international organisations aspire to the GMC standards” (HealthMedINT34). The GMC’s approach to QA was regarded by many stakeholders as well-considered. Stakeholders noted that the GMC’s work in quality assuring postgraduate medical education was highly developed in comparison with other international models. Certain factors were reported as contributing to the GMC’s advanced status, which included their organisational independence, years of experience, willingness to critically review their processes and being relatively well resourced. QAPs in both undergraduate and postgraduate settings reported that the GMCs role in quality assuring their organisations was influential, the GMC’s involvement acting as a lever for institutional change: “there’s no question about it, you have to do it because the GMC says we’ve got to do it and the GMC is our regulator. So it can be really helpful” (QAUG2). Working in partnership with the GMC was critical as it “has a significant effect on driving change in trusts” (HealthedUK21).

The **national training survey** (NTS) received widespread acclaim as it allowed organisations to drill down and pinpoint issues. It provided evidence to examine differences in training by local education providers and make evidence-based decisions thus increasing transparency, accountability and risk-identification. It was reported as being enviable, “It’s another green-eyed monster” (HealthNon-MedUK18), by national and international stakeholders both inside and outside healthcare. Having trainees’ perspectives was considered crucial by all stakeholders as these were “very useful eyes and ears” (HealthMedUK23) and could “identifying specific risks” (QAPG10).

Informal working relationships with the GMC were valued by QAPs. This included contact with a named person in QA at the GMC as well as employment liaison advisers. Informal relationships permitted the effective sharing of knowledge, reassuring QAPs their actions were appropriate and thereby supporting responsive quality improvements. QAPs noted that these relationships should not be underestimated. The regional approach to visiting was noted as a mechanism which fostered better relationships. The importance of informal relationships was highlighted as critical by other regulators too, “so we talk about having this annual discussion meeting and it’s largely about relationships... Well, it’s got a very important relationship building function” (EducationUK17). All stakeholders noted the importance of relationships for ensuring an inclusive approach to quality assurance and engagement.

Weaknesses

Weaknesses identified by stakeholders included: the conflicting nature of multiple QAFs, communication problems and issues associated with QA approaches driven by data.

The **conflicting nature of multiple QAFs** was highlighted. Organisations frequently reported the existence of more than one body quality assuring them, each with a specific approach to quality assurance, their own processes and priorities. Undergraduate and postgraduate QAPs had multiple regulators to attend to, each with their own QAFs (see Case study: enhanced monitoring, for the consequences of multiple regulatory frameworks). Health system regulators noted similar issues,

where organisations did well in one form of QA review and less so under another, causing confusion or disagreement. QAPs reported that, in some instances, there was blurring of responsibilities under the GMC's three-tier model and this could create complexity and role confusion. Information was sought about how the GMC internally quality assures across the model and within components of the QAF.

I suspect [postgraduate organisation] ignores them because they've come up with their own quality framework. QARC3

How does the GMC's assurance work differ or complement or overlap with that of other players, such as the CQC... Other aspects for me would be around how the GMC promotes consistency among the other organisations in the three-tier model. So is there cross-organisation training or moderation so that any interpretation of the standards is consistent? And how does the GMC build confidence in the model... [through] internal quality assurance, so the quality and reliability and validity of its findings? So who undertakes the visits, who checks their work and how their judgments are moderated. EducationUK31

There were several areas where QAPs felt that **communication** was weak. Formal GMC reporting structures were considered to be off-putting and acted as a barrier to sharing concerns. QAPs reported that feedback, particularly about self-assessment returns and visits, was important; a lack of, untimely or inaccurate feedback made them feel less involved and part of a "tick box" exercise.

Stakeholders agreed that an evidence-based approach to quality assurance was correct however some concerns were also raised. Multiple sources of data were sometimes regarded as obscuring an overall picture for the quality of medical education and training. It was highlighted that data only had currency for a limited period of time, for example, "if you're collecting, for instance, trainee data on an annual basis, when you go to the visits you could be a little bit behind what's happening" (HealthMedUK7). Another consequence of a **data driven approach** is the requirement for QAPs to provide that information. Some QAPs reported that returning data was a considerable burden and they were unclear what it achieved. Some sources of data were considered to have undue sway; vocal trainees, "red flags" or emergencies were reported to disproportionately impact on QAPs. A non-QAP highlighted that "I think they've just been focused really ...on things that ...have really been flagged up as a massive issue" (HealthNon-MedUK18). Concerns were raised about gathering data where clear outcomes or actions were problematic.

At the moment, they're [GMC] looking [at] trainee burnout. So they're generating all this data at the moment and I don't think they're clear about what they're going to do with it, and my concern is they will just dump it on us for us to fix, and I don't think we can. QAPG10

Accountability versus enhancement, proportionality and risk

The majority of stakeholders reported that the current trend within quality assurance is an **enhancement-oriented approach**. As such, stakeholders felt that resource allocation should favour enhancement activities.

The rationale supporting this approach was that standards on the whole were good. Even when organisational performance declined it was reported that an enhancement-oriented approach would provide better support. Enhancement-orientated approaches were considered to result in more effective collaborative partnerships and positive cultures. These views were held by QAPs as well as non-QAPs in UK settings and internationally. Stakeholders felt that medical education and training in the UK was of a high standard, “the regulator feels that standards have been driven up in the past ten to 12 years” (QAUG5) and this was explicitly embraced in another stakeholder’s “quality enhancement framework”. This positive shift, it was argued, supported a growing trend towards a “prevention agenda” (HealthNon-MedINT11) and upstream regulation. The enhancement agenda changed the tenor of relationships by limiting “the discipline that you have to do” (QAPG12) and ensuring “that the problem gets resolved in the most efficient way possible” (QARC24).

I'm completely with it...Or you can approach it from the right and celebrate the good practice, encourage innovation, encourage early adoption, and encourage...the laggards and get them to keep up. ...I would welcome any shift in focus towards the positive. Those triple greens and quadruple greens don't get half the attention the reds do, and it's a shame. QAPG16 We're trying very hard to portray ourselves as quality improvement, rather than just inspectors, it's... not perfect, but we're not here looking for perfection. QAPG14

However, even advocates of enhancement noted that the GMC shouldn't lose sight of its core priority, that of public protection.

Those who supported an accountability-oriented approach pointed to the (typically statutory) duty of the regulator to ensure minimum standards and provide reassurance to the public, a position regarded as particularly pertinent for the GMC and their patient safety agenda. Postgraduate QAPs, highlighted that in their sector things were more variable, less static and that there was “always a role for scrutiny” (QAPG28). This view was supported by one international stakeholder, who reported that enhancement was an activity that required a healthy baseline of performance, with enhancement being “the icing on the cake” (HealthMedINT1). It was thus felt that a focus on enhancement may detract from the pressing need to ensure that underperforming providers meet the baseline requirements.

Mechanisms for driving forwards quality enhancement approaches included allowing organisational autonomy to self-identify issues and implement processes to rectify them. Having structures in place, appropriate leadership and ownership were considered crucial in organisational quality enhancement. The regulator's role in supporting quality enhancement was assessing if there was organisational awareness of its issues, examining the adequacy of QA mechanisms, monitoring internal change as well as being supportive, signposting to relevant resources and providing constructive feedback.

We should expect the trust to know about its own problems. If they do, we know we can leave them alone, generally. QAPG16

The vast majority of stakeholders, across the sample, reported that they felt the GMC's approach to quality assurance was **proportionate to the risks involved in medical education training**. Proportionality was regarded as important because disproportionate regulation had unintended consequences, including a "drop in quality" (QAPG14).

A small minority felt unable to comment about proportionality with an additional small minority of QAPs feeling that the approach to quality assurance was disproportionate, relating to the weaknesses already mentioned above and the over-reliance on data that may be out of date or from disenfranchised stakeholders. Very closely linked to the idea of proportionality was the concept of **risk**. Risks in undergraduate education and postgraduate training were considered tangibly different; risks primarily being associated with postgraduate training and patient safety.

I guess they are, in visits, swayed by a patient safety issue that crops up. So again, a disproportionate weight will be put onto that. QAPG10

I generally think that there's less risk in undergraduate because they are more under the control of one organisation. Whereas postgraduate has a lot more players in the field. HealthMedUK7

The risks in postgraduate training were related to the pressure on and priority to provide clinical services. Patient safety issues were regarded as problematic for some QAPs because they felt "inadequately resourced to deal with patient safety issues" (QAPG16) and they considered these issues should be dealt with by organisations that were more appropriate like for example CQC. Other stakeholders noted risk was inherent in all education systems but patient safety was a "key distinction between the work that we do and the work that the GMC are doing" (EducationUK17) and that quality assuring education was different to medicine because of this issue. A line of enquiry in this study was to explore if stakeholders had models for **triangulating or predicting risk**. A small minority of organisations were sceptical about risk monitoring but most organisations were trying to develop models for the early detection of issues. Many were finding it challenging and reported its development a little way off:

We are developing one. So, we're doing some work on predictive data modelling at the moment. We haven't got an answer yet but it is a work in progress. So, looking at data to see whether bits of data that might indicate places are at higher risk than others. HealthMedUK26

3.2.4 Theme 2: components of the GMC's QAF

Theme 2 reports stakeholders' views about the effectiveness of the specific components of the GMC's QAF: standards; standards for equality and diversity; approvals; sanctions; monitoring including self-assessment; enhanced monitoring; visits; reporting; sharing evidence; good practice and collective assurance.

Standards

The standards were perceived to be "good" for the most part, by both QAPs and non-QAPs. QAPs described the standards as being helpful to guide their own QA practices, using them to guide

internal processes. Standards were regarded as comprehensive and detailed, acting as “clear guides of what should actually be happening in the trainees' day-to-day lives and in the arrangement and management of education, the leadership and the governance of education” (QAPG16). The standards create a framework for QAPs to check the viability of existing processes as well as serving as a benchmark for developing new ones.

The comprehensiveness and language of the standards led QAPs to conclude that the new standards were an improvement on the old ones. The standards also empowered QAPs at the local level. The new standards “now look at the environment rather than just specific areas like clinical supervision” (QAPG10) but also facilitate a wider *institutional* need to adhere to the standards. This need, combined with the more comprehensive standards, enables QAPs to push forward changes at their institutions and with their education providers.

The language that they are using in the standards, in comparison with the other regulators, it's straightforward. You know, we can read those standards and cut to the chase. We know what they are looking for.

QAUG29

Non-QAPs were complimentary of the GMCs standards. Speaking at the more philosophical level, the GMC's approach to standards was felt to be balanced and the flexibility of the standards was seen to be a strength, “it has allowed UK medical schools within the framework to differ in how they implement that framework” (HealthMedINT1). Non-QAPs raised the issue that, although standards are beneficial from a regulation perspective, they can be problematic in many ways for those being regulated. Standards that are overly prescriptive, rigid and inflexible are problematic as they prevent providers from being adaptable to need, as well as limiting innovation; but standards that are completely open and flexible can create too much variation in education and produce new risks to quality.

Consensus amongst non-QAPs was that the GMC's standards fell somewhere in the middle, navigating these risks in line with the approaches that other regulators take.

QAPs, however, were able to identify some specific weaknesses with the standards. QAPs could find it difficult to interpret standards and requested guidance from the GMC about demonstrating their compliance against the standards. This caused uncertainty and anxiety around how the GMC checked that they were meeting standards. Local pressures could also inhibit QAPs abilities to follow standards rigidly, suggesting that the “real world” applicability of these standards is sometimes questionable:

The general point is that you try to move away from anything that's too prescriptive but in writing things that are slightly more general, it is harder to use them as an accreditation tool. HealthMedUK6

A lot of LEPs take our students, but they can quite readily tell us to take them away as well, if we're very strict with them about meeting certain standards and certain criteria. QAUG5

Fairness

Overall the stakeholders had limited insights into how the GMC could quality assure fairness in medical education and training. Stakeholders were often unclear about what the question was addressing, sought further clarification and/or could not provide a coherent answer related to how fairness was part of the QAF. Discussions often focused on differential attainment, widening participation and how QA functions should encompass diversity e.g. within visit panels.

QAPs highlighted how politically, fairness impacts on all providers through legislation. Others felt that medical schools are already diverse and that GMC cannot regulate who applies to train to be a doctor and enter the system. The challenges of addressing differential attainment were stressed and QAPs emphasised the limitations in current knowledge about the causes of differential attainment, implying that QA of fairness requires a better understanding of the causes of unfairness in order to effect change. QAPs spoke of the fact that differential attainment is receiving greater attention in their organisation and is “much higher on the agenda than it was a few years ago” (QAUG15) and an obligation and responsibility of the providers, as well as the GMC to act on data was discussed so that they “don’t ignore data where it’s telling them that there’s an issue that needs to be resolved” (QAPG28).

Whilst non-QAPs also monitored equality and diversity they were unable to advance insights about how the GMC could further QA fairness.

Approvals

The GMC’s current approvals process was met with a degree of dissatisfaction from postgraduate QAPs. They criticised the lack of clarity on the definition of “approval” and when it would be required. For instance “well, what if the trainee goes for one week, but it’s only one week out of a one year placement, do they need to get that site approved?” (QAPG12). Others did not feel that the GMC adequately assured the quality of approved training environments.

We don't link approvals and quality very strongly...we go to the GMC and we say, can we put some doctors here please? And the GMC go, yes. But there's an implication in doing that that because we're asking, we're going to quality manage that particular set of placements. And we do, but not explicitly and not formally. QAPG16

Undergraduate QAPs were more positive about the GMC’s approval process. Whilst being described as intensive, examining both the curriculum as well as staff’s capabilities to deliver it, the thoroughness of process “enabled them to make a decision on our suitability to proceed” (QAUG29). QAPs were concerned that enforcing re-approvals in the undergraduate context would present practical problems that would be difficult to resolve i.e. closing medical schools, whereas postgraduate medical bodies were more supportive and could envision the advantages of time-limited approvals. These advantages included more accurate records of approved training sites and more control to move trainees by “building [time-limited approvals] in from the outset, that expectation that, you know, it might happen, would be beneficial” (QARC3).

Non-QAPs felt that regardless of whether or not approvals were time-limited it was important that mechanisms were in place to periodically review approvals and if this was in place to some degree a time-limit was less relevant (see Case study: approvals, reviews, visits). EducationUK31 noted:

The disadvantages are you will get [with time-limited approvals is] pushback from the training establishments that want to set up. You may have lots of extension requests. And you may have to repeat approval visits, registration visits, where the limit for approval has expired.

Case study: approvals, reviews, visits, risk

Case: Future directions of risk profiling impacting on frequency of QA activities such as time-based approvals, reviews and visits. Non-medicine, UK organisation, proportionate oversight with limited resources. **HealthNon-MedUK9**

Interpretation & lessons learned: This case pinpoints the need to tailor activities according to risk. Features of the providing organisation context (e.g. new/untraditional/risk markers identified from student/patient feedback) drove the response by the regulator as to whether to increase/respond with their activities or not. A review may be undertaken when the provider crosses one of these thresholds. The underpinning reason provided here is around risk of the provider. If the regulator perceives the provider organisation to be of high risk they are likely to escalate the activities undertaken. At first this may involve regular updates such as yearly visits. One of the ways the regulator seeks to reduce the burden of undertaking these processes on a regular basis is by setting the initial standards at a high level beyond minimum standards. This high level requires greater engagement of a provider to meet the standards so that they are approved. By assuring a higher level from the outset the regulator then has greater confidence that the provider will be a lower risk in future years. Although risk is seen at the core of the activities there may be reduced contact between the regulator and the organisation for the more experienced providers.

Illustrative quotes: *Essentially coming up with varying ways of differentiating providers and then looking at categories of risk, and then deciding whether or not an open-ended model of approval would be appropriate in the those circumstances.*

Sanctions

It was noted that organisational culture affects approaches to sanctions and so the idea of what is an 'acceptable sanction' is contingent on risks involved. However, there was a consensus between QA and non-QAPs that the most severe sanction of closure/withdrawal of students/trainees should remain. The "ultimate sanction of power" (QAPG28) is necessary to protect patient safety, reinforce the GMC's authority and consequently motivate providers to address problems. However, there was a firm belief that a severe sanction should rarely need to be enforced if other quality assurance activities are applied effectively and proportionally.

*It's a bit of a lightning rod situation, but I think it should remain as the ultimate sanction...If trust management realised for example that they wouldn't lose their trainees as a result of not providing a safe and effective training environment... I think [it would] slip further down their list of priorities. **QARC24***

So, there's sort of an approach that gives a warning notice, then you get the conditions, then after that it is the really serious enforcement stuff which is proposal to close an organisation. HealthMedUK26

Monitoring

Monitoring particularly through self-assessment was generally seen as a valuable component of the QAF. It created a governance and accountability culture within organisations. Monitoring kept providers “on their toes”, and “focuses the mind in terms of what gets measured, gets done” (HealthMedUK23).

Monitoring is a sophisticated practice, requiring in-depth experience of the field being monitored. Health systems regulators and Education stakeholders described how they use monitoring from a wide range of sources and organisations.

We are looking at information that is collected nationally, information from people that use services with feedback and also from other organisations to tell us what is going on in the practice, as well as the practice telling us what has changed. So, has there been new leadership and have they done something different? That helps us inform whether or not an organisation needs to be inspected or not ...if you are good or outstanding the process is much more monitoring. HealthmedUK26

Self-assessment was integral to monitoring and widely regarded by non-QAPs as a key part of quality assurance: “the most effective quality control mechanism, almost invariably, is your self-assessment” (HealthMedINT1); “a really fundamental part of what we do, and we place a massive... emphasis on that” (EducationUK17), I think it's an essential part of quality assurance” (HealthMedINT30) and “a vital and pivotal element in anything regarding quality assurance because this is the way an institution connects itself with given standards” (EducationINT32). The vast majority view was that self-assessment was a valid source of evidence.

Self-assessment was considered important by the vast majority of regulators because it generated an internally-led review (see case study: self-assessment, monitoring). This process had the capability to be more comprehensive than an external review, with organisations identifying and addressing their own challenges and deficiencies, and when done well promoted a sense of autonomy and accountability. It was a valuable tool because it looked at the everyday practices, could tap into the voices of educators and learners within that setting and could be a continual process as opposed to a one off look, such as a visit.

The self-assessment process also allowed the regulator “to work constructively with the provider...being the start of a peer review process” (HealthNon-MedINT11). An organisation that self-assessed critically was reported to give regulators confidence in the institution and the quality of education.

The institution needs to take that genuine look at it, and spend the time genuinely evaluating and genuinely creating action plans rather than using it as a way of saying, well, how can we cast what we do in the best possible light, you know? That's not what we're interested in...an institution that is

good at critical self-reflection will tend to address problems before, or potential problems, before they become actual problems. EducationUK17

In contrast, there were several problematic areas. The process may be ineffective if the self-assessment report glossed over problems and was “very circumspect” (HealthMedUK6) which limited its validity; “I suspect they view it as a complete hoop to jump through” (HealthMedUK7). Self-assessments that were regarded as “window dressing” (EducationINT32) were caused by an inappropriate “mindset and commitment” (OtherprofessionUK22) or simply the wrong person completing the paperwork. It could also reflect a weakness in organisational quality management and inadequate internal monitoring systems. Regulators reported that “a canny individual probably may be able to write a self-assessment that raises no concerns” (HealthNon-MedUK18) implying that there was a degree of subjectivity in the process. Writing self-assessment reports was regarded an “art” (HealthMedUK23), and getting it “right”, providing a balance between positive and negative issues.

From the QAPs’ perspective, a perceived lack of guidance about the level of detail, changing content requirements, lack of relevance, ambiguity and an absence of benchmarking resulted in tendency to view self-assessment more negatively than non-QAPs. The self-assessment report was time consuming, “we’re giving a lot of information to the GMC” (QAUG2), and reported as frustrating when QAPs had presented the “wrong” information. The GMC was often described as not providing sufficient feedback to the self-assessment, which was often interpreted by QAPs as not valuing their time and effort. Many of the QAPs were critical of the monitoring processes provided through self-assessment describing them as “an absolute nightmare...over the years...it seems to get worse rather than better” (QAPG10). Partly this was due to it taking a lot of time, involving a lot work, being cumbersome and becoming a “tick box” exercise. Self-assessment forms, too tightly scripted, failed to reflect contextual differences and ignored the bigger picture. These factors lead to disengagement by many QAPs.

One UK education regulator, recognising the issues described by QAPs, reported that their organisation had already moved away from requiring detailed self-assessment, or “remote monitoring” (EducationUK31) perceiving it as less effective than interaction-based approaches which have greater impact.

Regulators interviewed recognized that vulnerability may prevent disclosure. Experience and time helped organisations and QAPs to develop trust so that the providers felt more comfortable reporting concerns. For others the formality of a self-assessment report inhibited open disclosure “I think you’re more likely to hear genuine issues, genuine things that need to be fixed, if you speak to people informally and off the record” (QAPG6).

Nearly all stakeholders reported that self-assessment was not regarded as being reliable and sufficient to judge quality alone, it needed to be a part of the evidence base, “I think it forms part of it and it’s a very strong part of it, but I wouldn’t necessarily use it in isolation” (HealthMedUK23).

Judging self-assessments also required consideration:

How [does] the GMC validate self-assessment undertaken by organisations and whether the judgments against standards were standardised and

moderated? Does it provide exemplars, for example? And obviously, this whole concept of deans reporting, how do you triangulate that to ensure it's an accurate picture? EducationUK31

Case study: Self-assessment, monitoring

Case: Quality enhancement driving the integrity of self-assessment, future challenges troubleshooting (e.g. Brexit, technology), overlap with other regulatory reviews. **HealthNonMedUK9**

Interpretation & lessons learned: The case picks up on the value of streamlined constructive processes that are strategically aligned between quality partner organisations to reduce confusion and extra work. A regulator approaches self-assessment using a quality enhancement approach to promote self-assessment in a meaningful, constructive way. The example ties together many ways in which the regulator structures their position with the provider who is required to self-assess and report their QA processes. There are resources in place to be able to incentivise and reward the accurate self-assessment by provider organisations. The provider organisations are encouraged by the regulator to be open and transparent in their reporting of self-assessment so they can get the most out of the experience. The regulator admits a window dressing, best foot forward style is not what they are seeking. However, at first there is caution by the provider as they are uncertain of what will be publically reported. The idea is to show the strengths and weaknesses so that enhancements can be made. The participant explains they have to build up this confidence and trust over time and are able to use incentives to do this. Suggesting that confidence and trust both function as outcomes at the initial step and then move towards mechanisms to ensure the integrity of the QA reporting. The culture seems to be a key component for the organisation as they are keen to be as supportive custodians rather than penalising the provider. The experience over time may be needed to be able to demonstrate on behalf of the regulator and the provider that can work collaboratively and the honesty will be respected.

Illustrative quotes: *We are encouraging of institutions identifying challenges. So if an institution is very open and honest, even into what might be quite a delicate area, saying this has been a challenge for us and we're working away on it and we're doing the following things. Provided that their plan of action is a good one and that it's being conducted in a timely manner that would be reported on in a positive light.*

Enhanced monitoring

Whilst enhanced monitoring was generally seen as having some positive implications, it was often the component that came under considerable scrutiny from QAPs. It was often considered as problematic and ineffective. There seemed to be a real sense of confusion about what enhanced monitoring actually was in practice and how an organisation could be put 'under' and then later "escape" this process; "the trust I'm talking about was in enhanced monitoring for a statistical reason...the GMC that imposed that rather than a decision between us" (QAPG16); "the GMC seem

to be very reluctant to take a specialty out of enhanced monitoring” (QAUG5). Stakeholders frequently talked about the averseness of the GMC to act on outcomes from enhanced monitoring, the time-lag involved in the processes and how ineffective the process is to tackle patient and education risks.

Underpinning the effectiveness, or otherwise, of enhanced monitoring, were the mechanisms of “trust” and “surveillance” (HealthNon-MedUK9) and working in partnership with GMC to tackle problems. There were those who found enhanced monitoring effective particularly because working with the GMC could broker more power to invoke changes, by providing extra leverage with local education providers.

If as [role]...we're monitoring a trust and trying to get it to improve standards in education and training, if it ends up in enhanced monitoring it's because we've not been able to do it on our own, and then having the involvement of the GMC usually shifts things up a gear. HealthMedUK21

However, some spoke of their concerns around the impact of “bad publicity” and a negative impact on local relationships (see Case study: enhanced monitoring).

When stakeholders were asked if they thought the GMC overstepped its remit by requiring enhanced monitoring most other regulators felt it entirely appropriate:

Certainly not, because when there are concerns appropriate regulatory action needs to be taken. You've got to have a good enforcement process for when things are wrong, because this is about safeguarding people that use services, whether they be users of service for healthcare or users for getting education. HealthMedUK26

Case study: enhanced monitoring

Case: A hospital trust which had been regarded as outstanding by the CQC was put under enhanced monitoring because of a particular specialty programme underperforming. The specialty was the lowest performing across the UK. **QAPG16**

Interpretation & lessons learned: The case illustrates how important relationships are for quality assurance to be effective. The enhanced monitoring activities damaged the postgraduate quality assurance partner's relationship with the Trust. This case illustrates that data does not always have useful impact if it is used disproportionately to the remit of the provider organisation. One of the implications of a risk-based approach, which this is also, is that the regulator only ever acts as the “bad cop”. The data from the survey indicated a poorly performing area which a systems regulator then used to investigate further. The Trust were angered by this decision as it reflected badly on their reputation which had been shown by the CQC to be excellent. Further investigations seemed to confirm the issues were with the programme rather than the Trust. The limited flexibility of enhanced monitoring therefore created additional tensions between postgraduate organisations. This clearly damaged the relationship as there were contradictions in the different sources of data. The postgraduate QA partner in this case was unable to take appropriate action to be able to resolve

the situation at a local level. Enhanced monitoring needs to be appropriate to the issues identified so that accountability can be applied at the correct level.

Illustrative quotes: *If we were able to put [specialty] in enhanced monitoring, we could have lifted it from [UK hospital]. That would have helped our relationship with that trust, because it's been damaged somewhat by the application of enhanced monitoring...I think that's the key, is that enhanced monitoring, if it's going to be applied to anything, it needs to be applied to the right area, the right level and the right area of focus.*

Visiting

Visits were seen as a major part of the QAF. Visits were viewed positively as a means of enabling the GMC to verify data they had collected through self-assessment and monitoring. Whereas self-assessment often represented a singular perspective, a visit allowed the exploration of multiple perspectives, allowing corroboration of evidence, or triangulation, in a way that other quality assurance processes may miss. The opportunity to talk to other members of the organisation, teachers and particularly students, without organisational leads being present was reported as a critical aspect of visiting; enabling visitors to get a “feel” (HealthMedINT1) for what is going on. Visits were reported to be able to detect “low-level noise” (HealthNon-MedUK18) that would probably not be reported in self-assessment. Visits were regarded as triggers for internal review and reflection, motivating organisations to improve the quality of their education (see Case study: visits). However, visits also provided externality and an opportunity for peer review which was reported as important for public reassurance, particularly in the context of healthcare education.

There were a common set of mechanisms which were regarded as making a visit effective. Building partnerships was a fundamental aspect of visiting. Partnerships engendered trust with open and honest dialogue which was considered important in effecting change: “I was prepared to be completely open and honest with the GMC...If [visits] are going to be effective, relationship building is actually more important than what you’re doing collecting evidence” (HealthMedUK21). Meaningful dialogue and collaboration were important and that was achieved through having high quality, “respected” (EducationINT32) trained visitor teams. The combination of all these strengths led to the idea that the visit process is a crucial part of a QAF:

Outcomes require the provider to go away and do more work, but actually, it's being done in a way that means everyone's engaged with the process and feels like they've had a fair opportunity to put the evidence forward, but also understand from a regulatory perspective where issues are and why standards may not be met. HealthNon-MedUK9

I would see the visit as being the top of the tree. HealthNon-MedINT11

Stakeholders reported a considerable workload burden associated with organisational visiting, for the visitors as well as those being visited. The regulatory burden made visits “unwieldy” (QAPG26), a “disturbance” (EducationINT32). The delays incurred in organising them meant they often were an inappropriate tool when concerns had been identified. Stakeholders noted often it was the same organisations being visited by other regulatory bodies, and for struggling organisations quality

improvement was difficult due to staff shortages, high workload and there was a concern that visits were regarded as repetitive and as a punishment. The impact of visits could be undermined by unclear objectives, inadequate evidence, unclear assessment frameworks, under resourced visiting teams, miscommunication and being too superficial, “there's got to be an element of having a look a little bit further” (QAUG19). QAPs reported that greater tailoring or focus for the visits would be helpful and that feedback was key; a theme being developed outside healthcare too.

The way we're moving to much shorter focused inspections...they're not going to be quite intimidating as they have been in the past...it would be senior staff as well as junior staff to actually share...issues that...aren't being resolved and you can sort of build up a relationship with the education provider. HealthNon-MedUK18

The effectiveness of visits was validated when stakeholders were asked to consider what would happen if the GMC did not visit. A very small minority of stakeholders thought that the impact would be limited because of ongoing monitoring, regulation by other organisations or a healthy quality improvement culture in existence. One non-QAP organisation did not visit highly performing organisations. However, the vast majority reported significant concerns indicating that quality assurance was too complicated for paper and that monitoring processes may represent just one side story. Concerns included making the GMC more “remote” (QAPG14), undermining opportunities for building relationships and partnerships, “abdicated their responsibility” (HealthMedUK26) and weakening the system; particularly from the public perspective. Stakeholders reported that standards would eventually deteriorate because visits ensured that organisations “kept [their] eye on the ball” (HealthMedUK6).

Cyclical versus risk-based visiting was a hot topic with the stakeholders interviewed: “the same debates are happening in accreditation here” (HealthNon-MedINT11), the “eternal debate” (EducationUK31). There was a more obvious split between QAPs and non-QAPs: the majority of QAPs favoured cyclical visits, with the majority of non-QAPs favouring a risk-based approach.

Cyclical visits had support from around a third of stakeholders interviewed: “there's no talk from our perspective of making it entirely risk based (HealthNon-MedUK27). These formats provided greater alignment with enhancement-enhancement approaches to QA. The benefit of cyclical visiting was the personal contact with the regulator, visits making the regulator more “visible and accessible” (EducationUK31), and their relationship-building potential. However, cyclical visits had the disadvantage of becoming “stale” (QAPG14) and “promoting a sense of treading water, with a sense of nothing happening in between” (HealthNon-MedUK18).

A number of stakeholders suggested a blended or hybrid visiting model, in which scheduled visits could be brought forward or the frequency of visit cycles increased if the regulator detected a risk.

The risk-based approach was seen as being more economical, putting resources into organisations that needed them the most, catching organisations who are struggling and thereby making the greatest difference. Previous examples of thematic reviews provided justification that a more streamlined approach could be effective. Some organisations, inside and outside of healthcare, had already adopted an entirely risk-based approach, choosing to limit visits to organisations with evidence of high quality provision and strong adherence to the standards.

The system here is still based on a cyclical visit model, which we're looking to move to something that's much more evidence informed and intelligence driven, like the GMC. HealthNon-MedINT11

So if the risks aren't proportionate to justify the visit, then we'll not go along to the visit... Sometimes as a regulator you feel like you're just there because it looks good to have the regulator there. HealthNon-MedUK9

However, a problem associated with entirely risk-based visits is reducing opportunities to see high-performing organisations “perhaps limiting your ability to share effective practice” (EducationUK31).

Risk-based visiting was sometimes considered as being inappropriate in healthcare contexts because the regulator would be intervening too late. Risk-based visits also had “strongly negative connotations” (EducationUK17) often perceived as a punitive measure.

We no longer have that balance. We're not both the good cop and the bad cop anymore. We're just the bad cop. QAPG16

Thus, stakeholders at times linked the issues of risk versus cyclical visits with the overall approach to regulation: regular, cyclical visits driven by a collaborative, enhancement-oriented approach would appear to have the potential to foster a powerful relationship between the GMC and its partner organisations.

Visiting was a component under development. Training of visitors to ensure consistency was highlighted and was described as “pivotal” (EducationINT31) by both systems regulators and education stakeholders nationally and internationally in order to ensure that the judgements made were valid. This was done by using mechanisms like responding to external complaints about visitors but also through internal QA processes, including peer review.

We put the inspectors under quite a lot of pressure actually because we are asking them to evidence-base their judgements...the quality assurance panels are quite intense from the inspector's point of view and they have to present their findings. HealthMedUK26

Other organisations provided a visit aimed at supporting rather than directly assessing them, “technical assistance visits” and others had developed a more focused approach.

You're there onsite just to answer any questions and help the group out. So, ...to provide technical assistance...it's sort of an inverse risk thing, where someone believes they have risk and they reach out to us and ask for assistance. HealthMedINT20

Case study: Visits

Case: Feedback from the GMC following a visit led to positive changes in the medical school and with their clinical partners **QAUG5**

Interpretation & lessons learned: This case illustrates the importance of timely and constructive feedback from the GMC. Here, the feedback provided a motivating factor for driving change in the provider organisation. The participant described a situation whereby the clinical staff were starting to feel fatigue in what they were contributing. In response to this the medical school were trying to work in partnership with their clinical staff and reduce the educational burden on them. However, the favourable GMC report on aspects of their teaching provided a reward as they recognised the contribution. The impact of this feedback was that the medical school then paid more attention to the area and have since implemented the initiative on a larger scale. The feedback recognised the efforts, value and uniqueness of the contribution from the clinical staff. The medical school in turn recognised this and the clinical staff have since had increased motivation. The influence of the GMC is recognised here as having considerable power and can lead to changes at the staff delivery level. Without such recognition the situation may have remained static.

Illustrative quotes: *Instead of having it just as a first-year experience, it's now extended into second year. And that has been as a result of the positive feedback. So we went from something that the GPs were beginning to withdraw from to something that, simply because the regulator put a positive comment in their report, was highlighted as good practice.*

Reporting

The GMC's approach to the publication of reports on their website was generally well regarded. Having publically available reports demonstrated accountability and a transparent means of illustrating how providers meet the standards (see Case study: reporting data). A further advantage was noted to be building public confidence. Other regulators tended to have the same approach to dissemination but not all.

*I think the transparency in publications are important because it involves or it makes things clear and open to all stakeholders. **QAPG28***

*I think what having it public does, is it creates some pressure and accountability on both the accreditor and the accrediting body to focus on the outcomes and to show progress against conditions. **HealthMedINT13***

When reports included good practice, action plans, and were accessible for a lay or non-technical audience, then they were found to be most helpful.

A range of weaknesses emerged around what data is included in reports, and how it is reported. What is included in the final reports could paint a disproportionate picture of the organisation, for example if minor issues are reported when the findings were mostly positive. Reporting needs to be timely and appropriate to the level of risk, for instance reporting something publically could damage

the organisation's reputation unnecessarily if the issue has been addressed swiftly. The implications of reports need to be fully considered before release and contain no surprises.

The relevance, purpose and clarity of what data is reported was questioned by those within and outside medicine. Although transparency was favoured there is a danger of publishing excessive information which makes it confusing for the audience to understand; "there's almost too much of it [reporting] there, in terms of how someone makes sense of what the GMC are doing" (HealthNon-MedUK9).

There is a relatively bigger audience for summaries, but the long reports have so far a very... For let's say the inner circle, they need all the information and for the public, they like it when they have a short summary at the beginning. EducationINT32

The way information is communicated has implications if the audience is misaligned. For example, if training is not separated out from patient care/service delivery in the reports, this can be misunderstood by lay audiences. This highlighted the need for the reporting to be appropriate to the context of the audience (e.g. medical schools, general public, students, government) and making it accessible for different stakeholders; "I'm not sure that those reports are very accessible for people who are working outside of medical education" (QAUG5). How the GMC presented organisations in its reports, the tone and balance, had a direct influence on trust and relationships.

It was felt that short to-the-point summary reports were helpful and need to be written in a more accessible manner. The data reported is not always comparable with data from other institutions because of their differing processes, "you're comparing apples and pears sometimes" (QAPG10). Some stakeholders felt that the data published by the GMC was not always scrutinised enough, and could be better linked up with other information sources to be clearer for their audience; in other cases some data was felt to be irrelevant. QAPs spoke of how there was disappointment in their regions that examples of good practice that had been identified were not featured in the outputs, and that this can have damaging effects for student recruitment and trust.

I don't think there's a huge sense of kind of putting reports in context and linking them up. There's a tendency to sort of throw them out there and, I think, in some ways hope it has some value. QARC3

Rating scales seemed to be less favoured as a way to report data. Weaknesses included the issue of a ranking "TripAdvisor effect" (QAUG19) where opinions could be unduly skewed by organisations playing the system, by addressing certain metrics, misleading not reflecting current situations, duplication of information from other rating scales and the subsequent reputational challenges as "training quality is possibly a marketing device as well" (QAPG28). It was also noted that simplistic rating tended not to capture nuances, and can be particularly frustrating for borderline cases. The ability of the public to interpret complex data was also reported to be problematic.

I just think they need to be mindful of how they report when they report by UK country. So I guess if they were to come out and say...this is great in

England...lots of work that goes on in England, even if it's positive, can have a negative effect on Wales, possibly Scotland, Northern Ireland. **QAPG10**

Case study: Reporting data

Case: Transparent reporting of QA data, GMC and non-GMC comparison, public appearance, competitive market place, different legislation, accessibility, readability and purpose of reports, European Guidelines for Summary Reports and Comprehensive Reports. **HealthNon-MedINT11** and **EducationINT32**

Interpretation & lessons learned: This case highlights that transparency is vital to ensure public confidence in the GMC's regulation. However, reports need to be accessible to the appropriate readership. A non-UK based organisation produce summary reports on their website and only provide full reports back to the provider. There are fewer legislative requirements which may underpin the decision for this level of disclosure. However, this situation means that the public and other organisations do not have access to make informed decisions. There is a lack of transparency as the summary reports may omit information that is desired. The participant contrasts this use of reporting with the GMC's approach where the full reports (e.g. NTS) are made available for everyone online. This is thought to enable much more transparency as anyone can access the information and investigate further.

However, there are a range of issues which influence comparative data in reports. Within the international context, for example, there are many providers within different states competing with one another. There is a perceived need to withhold certain aspects of information to account for the quality of the provider. An accreditation organisation therefore changes the language thereby framing quality assurance as more of a quality improvement process. The reports provided by another regulator take into account guidelines produced for QA agencies which highlight the need for accessibility and readability. The implication is that there is much more information relevant to "judging" an organisation and that documentation from the GMC needs to take account of the wider context in which the provider is undertaking their activity.

Illustrative quotes: *I think it's really good, really transparent, and that's how it should be. I like particularly all the stuff they've done around the NTS and the different ways in which people can cut the data themselves and all those kinds of things, and I think publishing the long-form reports provides good transparency.*

One stakeholder pointed to research in this area: transparency of European higher education through public quality assurance reports. This research identified that external stakeholders wanted short concentrated summaries tables of numerical data about important aspects of organisational performance will programmes and comparable data. Internal stakeholders however needed long format reports. For further details see: [http://enqa.eu/indirme/papers-and-reports/occasional-papers/Transparency%20of%20European%20higher%20education%20through%20public%20quality%20assurance%20reports%20\(EQArep\).pdf](http://enqa.eu/indirme/papers-and-reports/occasional-papers/Transparency%20of%20European%20higher%20education%20through%20public%20quality%20assurance%20reports%20(EQArep).pdf)

Sharing evidence

QAPs had mixed views about how well evidence was shared with them. As previously stated most of them were positive about the NTS and believe it to be an impressive tool that generates a huge amount of data that they can make practical use of (see Case study: sharing evidence). Another QAP was satisfied with the way that the GMC shared soft intelligence with them during meetings, that is, unpublished information that may be anecdotal in nature. Conversely others felt that the extent of information the GMC share with QAPs comes solely from the NTS and nothing beyond.

The GMC have a meeting once a year when they call out some of the real poor performing posts and they shared that stuff with us only recently, a few weeks ago, and that meeting was very helpful and I think on a discussion level, the GMC also share soft intelligence with us. Things that ...from the data...they're noticing. QAPG28

When asked about sharing evidence between healthcare regulators, QAPs recognised that the GMC must strictly maintain data protection but there was a feeling that postgraduate medical bodies wished to find an appropriate way for the GMC to share concerns with them in a confidential manner. QA organisations outside of healthcare noted the importance of having a clear purpose for data sharing and clarity on data ownership.

I think there needs to be a consideration of how the GMC are able to share information more effectively of concerns with a regulator. It is not to put it out in the public domain but in a very confidential way to share information so that we know. HealthMedUK26

Case study: Sharing evidence

Case: Healthcare and non-healthcare organisations sharing evidence thereby reducing duplication of requests on providers' time, identifying risk earlier, reducing workload burden, data relating to funding targets, quality, outcomes, educational objectives, etc. **QAPG14**

Interpretation & lessons learned: The case demonstrates the need for the GMC to effectively share evidence with other QA bodies to reduce burdens and identify risk at an earlier stage. The data required by providers is not always the same each year therefore providers often have to predict what type of data will be requested in subsequent periods. Collating required data can take time as the organisation may not have been collecting the information in the correct format. This case illustrates how the data requested by one organisation was then used by another to assure quality of the provider and identify risk. The provider thereby met the standards through sharing of data. The data reported was seen as valuable by the regulator and was regarded as robust enough to base their decisions. This acceptability of data collected by a third party was facilitated by the flexibility of the regulator to accept information they had not requested themselves. By accepting data from third parties this in turn reduces the time and effort required by provider to duplicate their efforts. The institution can produce one report which is then used for multiple purposes.

Illustrative quotes: *We've got a group called sharing intelligence and we get together with our other regulators and bodies...mental welfare commission, social services, ombudsmen...to look for*

organisations that may be beginning to struggle...It came out of the Francis work that we now have a look, we now have a cross system and we feed the GMC's data into that conversation.

Good practice

In principle, there was mostly agreement across the board that sharing good ways of working is valuable. The issue of how to define “good practice” was raised across the full range of stakeholders. Some QAPs felt that there was ambiguity in what the GMC consider to be examples of good practice.

I think sometimes what's one person's good practice is someone else's business as usual, isn't it? Definitions around good practice are very, very difficult. QAPG10

Motivation was low across a range of QAPs, to implement changes based on good practice recommendations. Barriers included the perceived irrelevance of good practice to their own organisational context, a lack of understanding on how to apply changes, and difficulty in accessing good practice outputs. QAPs did not readily access the GMC's examples of good practice on their website and would like to see more innovative ways of sharing this information and more opportunity for stakeholders to meet and discuss good practice.

Higher education organisations had a range of methods to disseminate and communicate their examples of good practice and acknowledged that good practice is not about solving problems but offering alternatives.

We run a series of activities over an academic year to promote good practice and to help institutions work together to address any recommendations...we've got a whole series on our website of, you know, webinars, videos, short publications, postcards, materials, that are designed to share good practice and, you know, to swap ideas. They can pick them up and make use of them as they wish. EducationUK17

The contextual nature of good practice was identified by several non-QAPs:

What works for one school may not work for other ...So, you don't want people to blindly be saying oh, let's do that, because that's going to be good practice here....Because education in programs do vary. HealthNon-MedUK18

And we've tried to be careful to show a range of approaches that may be equally effective. And it's important for people to understand that what may work in one setting, may not actually work in another. Because it's all bound up by the effectiveness of the leaders, the culture, and the context of the setting in which that practice is being implemented... So we would identify effective practice through research. EducationUK31

Collective assurance

Improving efficiency and reducing the workload in quality assurance activities was a pressing issue for all stakeholders. To this end, across QA organisations/healthcare regulators the idea of conducting activities jointly was welcome in theory but one that is not commonly practised yet. There were numerous practical concerns raised. As previously mentioned, monitoring was thought to be an activity that would lend itself well to being a joint activity. Some stakeholders suggested that they could save time filling out various documents if a single reporting tool was devised that allows multiple QA bodies to access this information and use it in multiple ways.

I think we agree, between us, that there will be one process and that one of the regulators assumes responsibility of all three. That would be the next step there. **HealthMedUK6**

So they're having to report similar sets of things, multiple times, rather than an agreed set of things once, which is then used in multiple ways. It's easier in theory than practice because there's got to be a lot of agreement about what's collected, who collects it and how you access it for different means.

EducationUK8

There was less support for regulators conducting joint visits across all stakeholder groups. Some found it difficult to imagine how this would work across different healthcare professions without increasing resources and impacting on service delivery.

I struggle to see how we could share events across kind of major professions where they are quite different. Even though, from a kind of syllabus perspective, they kind of look quite similar, actually they are not.

HealthMedUK6

However, one regulator regularly conducted joint visits with at least four other major regulators. They reported that joint visits could be more accurate and draw on visitors' different specialist knowledge enabling a more complete picture of the organisation being visited, as well as affording the "opportunity to learn more effective ways of doing things from inspectorates" (EducationUK31). Downsides of joint visiting were reported to be an element of confusion for the provider, challenges of accessing original evidence rather than summary documents and collaborating to complete a final report agreed by all. If an organisation's performance was satisfactory in one field but needed improving in another their considered opinion was that it may be better to do separate visits, despite the regulatory burden, in order to provide more detailed support for organisational improvement.

One QAP spoke of how they are working towards joint visits with other medical schools to quality assure undergraduate placements.

3.2.5 Theme 3: suggestions for improvement

This theme reports interview stakeholders' suggestions for how the GMC can advance their quality assurance activities.

Clarity on roles and boundaries: A major theme across all stakeholder groups was the need to improve clarity across the QA processes as exemplified by the QAF's three tier model. There were suggestions about having clarity and agreement on the remit of each organisation involved in medical regulation, each having an understanding of what each other does and where responsibilities begin and end.

You have to remember what your remit is. Potentially you can get conflicts there if you're not really careful. HealthMedUK26

Streamlining processes: As referred to in the section on collective assurance, QAPs noted the GMC's QA activities could be better aligned with that of other bodies also regulating them, and that this is worth exploring to achieve greater efficiencies. Other stakeholders recommended similar:

Clarifying why we need slightly different things, and sometimes it's about one or other of us saying, well, if you're producing this piece of information for that body, then that's good enough for us and we won't ask you to do the same thing again. EducationUK17

Stakeholders reflected how an over-arching body could play in coordinating regulatory QA activities:

It might be the Department of Health does that, or somebody which has oversight of everything, which can bring the regulators and the regulated together. QAPG14

Self-assessment: QAPs recommended shorter self-assessment returns and greater feedback which would lead to greater engagement. They requested advance notice of any new lines of enquiry that the GMC were exploring in order to better prepare replies and non-QAPs recommended providing illustrations and examples of the desired/required responses.

Standards: the GMC to provide clearer guidance about interpreting and demonstrating compliance with the standards. Another suggestion was to consider whether a single set of standards could be developed across healthcare professions that may help decrease regulator burden.

Use of existing data: for example, the NTS could compliment the GMC's monitoring processes providing another large dataset, balancing self-assessment with students' perspectives and aid risk profiling.

Improving visits: QAPs had views about how the GMC could facilitate a more two-way interactive visiting process between them, from better preparation to follow up post-visit. The visit team was considered crucial to making visits effective. Suggestions were made about increasing visit team diversity, the involvement of Royal Colleges and Postgraduate Deans and including lay representation:

Maybe some sort of lay, you know, what's your perception of the graduates? You're a simulated patient working with these. You're part of the public engagement group of the medical school. What's your level of involvement? What's your perception of what's going on? I think that gives a different perspective in terms of what's happening. QAUG5

Feedback and informal relationships: opportunities to enhance feedback and informal relationships were critically important and mentioned by all stakeholders. Opportunities to enhance these have been identified within the body of the report but a specific recommendation is given below:

It's just the lack of feedback. It doesn't feel an engaged process. And I think if they're not doing site visits, if they had a network of QA people in each medical school, I think you would have a more involved process, and people would engage with it more and take more responsibility for it. QAUG19

Internal quality assurance mechanisms: more explicit guidance about how the GMC internally quality assures its activities; how it makes and moderates judgements, trains its visiting team.

4. Discussion

In this section we address the original research questions. We have merged questions 1 and 2. Research Question 8 is addressed in the implications.

RQ1. What are the strengths and weaknesses of the GMC's quality assurance framework?

Overall there was recognition that the GMC has robust practices in quality assuring medical education and training. The GMCs QAF was commended for being comprehensive, and one that enabled a broad understanding of an organisation's performance. The components were viewed as appropriate and familiar to all stakeholder groups, no one suggested that an aspect was missing. QAPs appreciated the clarity of the QAF and the three tier model fostered a good understanding of the remit each type of organisation plays in QA. QAPs agreed that the standards were the right ones and the focus on outcomes helpful, but there was some scepticism from some QAPs about how to demonstrate that they met the standards. All stakeholders noted the importance of relationships for ensuring an inclusive approach to quality assurance and engagement. There were mixed views from QAPs about how well this was achieved, but they certainly valued informal working relationships. Across the board, visits were noted as a mechanism that could foster better relationships.

The main weaknesses and problem areas identified fell broadly into two themes, those related to the overlap between QA bodies and those related to the regulatory burden on QAPs associated with data driven approaches to QA. Organisations reported the existence of more than one body quality assuring them, each with a specific approach to quality assurance, their own processes and priorities. Undergraduate and postgraduate were regulated by multiple QAFs causing frustration at the repetitive nature of QA exercises and a workload burden for staff. QAPs criticised the blurring of

roles and boundaries between multiple organisations that QA medical education, training and patient safety. This lack of clarity led to confusion, disagreement and feelings of undue regulatory burden. Most people agreed that an evidence-based approach was appropriate and necessary; however, concerns were expressed about the monitoring aspects of the QAF. Among QAPs there was a unanimous feeling that they have to provide too much data to the GMC and that there was a lack of transparency on why and how this data would be used. It was highlighted that data becomes outdated and/or problems have been dealt with by the time a visit is conducted or the GMC's report is published. QAPs were concerned about unintended consequences of GMC reports written in a way that was perceived to be unbalanced. Examples were cited of times when emphasis was placed on problem areas; this damaged their reputation and relationships with other bodies.

The findings presented here reflect stakeholders' perspectives but there is a lack of output data to associate links. Further work is needed to explore the complex links between QA activities and outcome data (e.g. NTS, CQC data) and how these relate to QA. The voice of the patient, public and student are also not taken into consideration in this research as we focused on systems level regulation.

RQ2. What suggestions, if any, do stakeholders have for improvement?

Suggestions for improving the GMC's approach to QA mainly came from QAPs who had the greater insight compared to external stakeholders. Most recommendations were on the topics of clarifying roles and remits, streamlining processes and promoting transparency. Viewed as the foundation for effective collective assurance, was the need for QA organisations to have clearly defined remits and a shared understanding of what each other does and where their own responsibilities begin and end. QAPs spoke at length about the inefficiencies in QA generally, and were keen to suggest ways of how to streamline processes to reduce workload burden and improve the impact of QA activities in their own organisations. Underpinning suggestions was the common idea that a tailored approach to QA activities would lead to greater efficiencies. It was noted that the risk to patient safety was different between undergraduate medical and postgraduate sectors, and that this was worth reflecting in the GMC's QA activities. Many people spoke of feeling like the information they provide is duplication, so collaborating with universities, trusts and the CQC to standardise monitoring forms where possible was welcomed. Also suggested was making use of existing data where possible. QAPs felt that self-assessment could be stream-lined and timely feedback would lead to greater engagement. Standards were thought to be appropriate and much improved, however postgraduate organisations wished to see clearer guidance on how to interpret them for their own organisation, so they can clearly demonstrate they are meeting requirements.

QAPs valued transparency and it was thought that the GMC could improve on sharing evidence. Currently, QAPs felt that they are asked to provide a lot of data and do not understand for what purposes it will be used. There were also questions around how the GMC maintain validity and reliability within their own QA processes. Other healthcare and education regulators echoed that transparency from the regulator builds trust with those they regulate and that this has positive effects on working relationships.

A few participants highlighted that when undertaking QA activities the GMC should maintain diversity within their own teams.

RQ3. What are stakeholder's views on the quality assurance of standards for equality and diversity?

Fairness, equality and diversity were identified by the GMC at the beginning of this study as being embedded across all of their quality assurance activities with a particular focus on learning environments and fairness in training pathways. Overall the stakeholders had limited insights and often struggled to provide a coherent answer related to how this issue was integral to quality assurance. The stakeholders recognised the importance and challenges of addressing differential attainment and widening participation in medical education and training but often did not appoint this within the current remit of the GMC. There were several reasons as to why this was the case. Despite increasing awareness, a large gap in the knowledge base remains therefore it is extremely difficult for regulators to impose any meaningful and worthwhile requirements on providers when tackling fairness. Government legislation requires organisations to adhere to the Equality Act 2010 hence ongoing processes are already in place. There are also contextual factors which impede efforts such as the geographical location, under-represented groups and workforce shortages that may be beyond the control of both QAPs and the GMC.

RQ4. How effective and proportionate is the approach to quality assurance?

As previously stated the effectiveness of the GMC's approach is difficult to arbitrate given conflictual organisational approaches that carry out the same or similar functions. The GMC's approach to quality assuring medical education and training was largely considered proportionate to the risks involved. Ongoing relationships and communication were strengths of the QAF which enabled the GMC to work closely with providers, such as monitoring and cyclical visits. The GMC's engagement with QAPs was an effective mechanism for change. External assurance activities have previously been linked to the development of internal quality processes (see Blouin *et al.*, Griffin *et al.*).

Findings revealed that self-assessments were seen as vital however should not be used in isolation, this was echoed in the literature review regarding concerns on the validity and reliability of self-assessment (see Jones *et al.*, 2017). Data gathering activities such as the NTS help to pinpoint risk areas for further investigation at the postgraduate level. When risks are identified appropriate processes are in place to sanction and remediate struggling organisations.

QAPs were often somewhat more critical on how proportionate the approach is compared to non-QAPs, particularly in the areas of monitoring and enhanced monitoring. Monitoring often had a workload-time burden with the questionable relevance of unclear information requests followed by a lack of GMC feedback leading to provider disengagement. Additionally, enhanced monitoring was regarded as being unclear and ambiguous in regards of the added value it provided to quality assurance, other than being under the microscope. While collective assurance and sharing were seen as excellent initiatives, the existing GMC processes seemed to be lacking in this domain although useful alternatives were provided by non-QAPs.

Questions over balance between enhancement and assurance remain. While some interviewees described them as being on a continuum (improvement/enhancement at the upper end of a quality continuum, and assurance/ensuring minimum standards at the lower end), Lang (2015) suggests that they are fundamentally in conflict: improvement/enhancement tend to drive innovation and

hence variation/heterogeneity, whereas benchmarking tends to produce isomorphism (organisations adopting the same processes/approaches/structures). Forrest (2015) also notes that organisations that become fixated on meeting minimum requirements are unable to focus on other important non-standards based activities.

A number of interviewees suggested a hybrid approach to cyclical v risk-based visits, but with scope to bring forward or increase the frequency of visits dependent on indication of risk. The finding aligns with Ehren *et al.* (2015) that a combination of cyclical and risk-based visits was more effective than cyclical alone.

RQ5. Would collaboration with other professional bodies/ system regulators improve effectiveness and proportionality?

There was a unanimous view that collaborating with other QA bodies made sense and that if organised well, could streamline processes and reduce regulatory burden for all stakeholders involved. However, the view is that collective assurance in healthcare regulation is underdeveloped. There is little to no evidence base that can provide guidance on how different bodies can work together to improve effectiveness. While QAPs made suggestions on aspects of QA that could be shared (in previous sections), many of them were sceptical about whether these were practically achievable. It was noted that health professions were not one and the same entity, and that it was likely that each profession would need to retain its own QA processes at some level. There were mixed views about joint visits, some partners were unable to envision its relevance in the medical context, others were able to imagine how regulators from professions with similar patient contact (Dentistry, Nursing) could add value. Only one representative, an education regulator, had a more developed approach to sharing inspections/visits and reported significant advantages but also spoke of the challenges.

RQ6. How does the GMC's approach align with current best practice in quality assurance?

In this study we have interviewed a wide range of UK and international QA stakeholders within and outside medicine who generally seem to acknowledge the robustness of the GMC's approach to QA. The non-QAPs were positive about the GMC's approach and the comprehensiveness of the various functions. However, within certain components there is room for advancements that may enable the GMC to substantiate its position.

Jones and Tymms' (2014) realist evaluation found that regulatory activities associated with improvement included: setting standards; the provision of feedback; employing a system of sanctions and rewards; monitoring schools by the collection of information; and public accountability. Many of these mechanisms (other than rewards) were present in our findings. Griffin *et al.* (2017) also found that visits drove quality improvements via self-assessment and internal quality review. Again, within our data we found visits driving various individual and organisational reactions, leading to quality-related activity.

RQ6a. How does the GMC's approach compare and contrast to other selected national and international established practices within healthcare?

Within healthcare the GMC appears to have robust QA practices, equivalent to if not better than other health regulators. From international perspectives there was wide acclaim for the GMC's data collection and the transparency in their processes. Although from a relatively small international sample, the GMC was seen leading the way. For instance, many organisations admitted to not considering fairness, collective assurance and reporting full data sets online.

Within certain UK jurisdictions there were examples of closer working partnerships across undergraduate and postgraduate organisations which helped to identify risk and also spread good practice. The importance of relationships and regulators working collaboratively with partner organisations was also highlighted in the literature review (Forrest, 2015).

The scope of the GMC was questioned and which parts of medical education they should be quality assuring. Similarly to the GMC, other healthcare regulators are considering ways to advance their approaches and are undertaking reviews of current processes. The main area of focus appears to be on the risk/proportionate/collective assurance alignment agenda largely underpinned by resource implications but also ways in which enhancements can become encultured within healthcare education.

RQ6b. How does the GMC's approach compare and contrast to other selected national and international established practices external to healthcare?

The study identified that practices external to healthcare were particularly developed in the education field. Both nationally and internationally education organisations appear to have tackled many of the conceptual issues discussed and fostered alternative approaches to test out effectiveness. Collaborative visiting allowing organisations from different fields to occupy the same activity for their own agendas and was seen as useful way to reduce burdens. Additionally, the sharing of data collected for different purposes helped to develop a more detailed understanding of the risk posed by a provider. European standards for reporting were highlighted and the ways in which data can reach those who need to understand it the most.

5. Implications of findings

The implications for collaborations and partnerships: effective working relationships foster trust and allow the early communication of emerging risks and support quality enhancement approaches. Cyclical visits aid communication and build relationships and if lost may distance the regulator and undermine opportunities for partnership working. **Informal lines of communication** provided a safe environment for QAPs to discuss concerns with the GMC as they arose as opposed to formal monitoring and self-assessment which sometimes acted as a barrier to effective communication. Openness between the provider and the GMC can help to bridge the gap from policy into practice. Relationships between providers should be encouraged so that the field can tackle issues conjointly rather than alone.

Implications for working within the three-tier model: within the postgraduate setting there needs to be further consideration and clarifying communication about how different organisations are intended to function in relation to quality assurance and quality management so that there is less duplication and confusion of responsibilities.

The implications for equality and diversity point towards making fairness more explicit within quality assurance activities and having action points that directly relate to equality. Further work is needed to understand how equality and fairness relates to quality assurance and to distinguish which aspects can be regulated, if at all e.g. workplace bullying. The current approach portrays fairness as a tacit driver with no real way of provider organisations to meet minimum standards, or demonstrate progress. For the GMC to tackle issues such as differential attainment, widening participation, and equality within training environments clearer guidance is needed about how the GMC will regulate these particular aspects. The focus again could be on outcomes (e.g. demographic representation and progression) or processes (e.g. diverse panel members on selection panels) and explicitly quality assured in alignment with other aspects of the framework (e.g. standards, monitoring, reporting).

Implications for monitoring and self- assessment: the regulatory burden associated with monitoring activities was considerable and disengagement was apparent. The repercussions of retaining the current processes are that the GMC will receive insufficient data by which they can quality assure partners. A lack of **feedback** was an important aetiological mechanism precipitating the current situation and is a suggested area for consideration.

Implications for visiting: the wider trend in QA is for **risk-based visiting** but this has consequences for the GMC. Risk-based approaches could decrease opportunities for interaction and meaningful dialogue across the QAP cohort, lessen the chance of identifying good practice and may undermine a collaborative approach to QA. In the analysis risk-based visiting was reported to position the regulator as quality assurer rather than an organisation supporting quality enhancement and this could have further negative impact upon relationships. Enhancement-led approaches prompting organisational autonomy may negate the need for more labour-intensive activities. Therefore, collectively considering a hybrid model of cyclical plus risk-based visiting may help to build provider relationships and drive improvement while also ensuring minimum standards.

There were implications for visiting teams, their composition, training and standardisation of decision-making in terms of fairness, diversity and equality of judgements.

Risk, however, is context dependent and was perceived to be tangibly different across undergraduate and postgraduate settings. Undergraduate medical settings were perceived of as low risk and imply opportunities for greater tailoring and focus.

The move towards risk-based approaches is further complicated by accurately and reliably gauging risk which is reported to be challenging and an area in development. Risk metrics are important but sometimes fail to identify emerging risk and don't take into account soft intelligence for which informal networks have been highlighted as crucial.

Implications for reporting: long-format reports are important for QAPs. However, this method of reporting is less readily digestible for external audiences. If the GMC wishes to communicate more effectively with for example, medical students, trainees, other key stakeholders, then summary reports and comparative data would be desirable.

The implications for sharing best practice: best practice is contextually dependant and explicitly providing examples inadvertently displaces practices and processes approved by the regulator and may be inappropriate for some QAPs. The implications of this, as well as underused internet

repositories, may be to develop more interactive face-to-face facilitative clusters and to provide a diverse range of examples so QAPs can share and contextualise best practice.

Implications for collective assurance: there is a need to conduct a comprehensive economic review and consult further with health and non-health regulators into what data could be shared and whether the quality assurance benefits would outweigh time/costs. There are many theoretical advantages and stakeholders are overwhelming positive, but there are significant practical challenges in practice. **Flexibility** in utilising other datasets within any collaborative work is a necessity and a clear stance on organisational remit and particularly boundaries, is anticipated to be a key mechanism in effective joint quality assurance.

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7. Appendices

CONSENT FORM

Title: Understanding stakeholder perspectives on GMC’s quality assurance of medical education and training.

Department: Research Department for Medical Education

Name and Contact Details of the Principal Researcher: Dr Ann Griffin- a.griffin@ucl.ac.uk

Name and Contact Details of the UCL Data Protection Officer: [Lee Shailer data-protection@ucl.ac.uk](mailto:Lee_Shailer_data-protection@ucl.ac.uk)

This study has been approved by the UCL Research Ethics Committee: Project ID number: 6281/003

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in.

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

- I confirm that I understand that by ticking/initialling each box below I am consenting to this element of the study.
- I understand that it will be assumed that unticked/initialled boxes means that I DO NOT consent to that part of the study.
- I understand that by not giving consent for any one element that I may be deemed ineligible for the study.

		Tick Box
1.	I agree to the following statements: <ul style="list-style-type: none">• I confirm that I have read and understood the Information Sheet for the above study.• I have had an opportunity to consider the information and what will be expected of me.• I have also had the opportunity to ask questions which have been answered to my satisfaction.	
2.	I agree to take part in a one to one interview lasting approx. 30-40 minutes.	

3.	I agree to the following statements: <ul style="list-style-type: none"> • That quotes from my interview can be reported in an anonymised manner. • The organisation I represent may be named in reporting documents but I will not be personally identifiable • That my interview data can be written up as an anonymous case study if selected by the research team. 	
4.	I consent to my interview being audio recorded and understand that the recordings will be destroyed following transcription.	
5.	I consent to the processing of my personal information for the purposes explained to me and I understand that such information will be handled in accordance with all applicable data protection legislation.	
6.	I understand that my data gathered in this study will be stored anonymously and securely.	
7.	I understand that confidentiality will be respected unless there are compelling and legitimate reasons for this to be breached. (If this was the case we would inform you of any decision that might limit your confidentiality).	
8.	I understand that my data will be anonymised and that all efforts will be made to ensure that both myself and my organisation cannot be identified so that it will not be possible to identify me in any publications, reports or conference presentations.	
9.	I understand that my participation is voluntary and that I am free to withdraw at any time up until 31 st August 2018, any personal information and data I have provided up to that point will be deleted unless I agree otherwise.	
10.	I understand the potential risks of participating and the support that will be available to me should I become distressed during the course of the research.	
11.	I understand that the data will not be made available to any commercial organisations but is solely the responsibility of the researcher(s) undertaking this study.	
12.	I understand that the information I have submitted will be published as a report and I wish to receive a copy of it. Yes/No	
13.	I am aware of who I should contact if I wish to lodge a complaint.	

Name of participant

Date

Signature

Researcher

Date

Signature

INFORMATION SHEET

Title: Understanding stakeholder perspectives of the General Medical Council's quality assurance of medical education and training

Department: Research Department for Medical Education

Name and Contact Details of the Principal Researcher: Dr Ann Griffin- a.griffin@ucl.ac.uk

1. Invitation

You are being invited to take part in a research project being conducted by staff at UCL's Research Department for Medical Education; the purpose of which is to gather a range of perspectives about how the General Medical Council (GMC) currently undertakes their role of quality assuring medical education and training in the UK. Participation is voluntary but, before you decide, it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please do ask us if there is anything that is not clear or if you would like more information.

2. What is the project's purpose?

The General Medical Council is responsible for quality assuring medical education and training in the UK. They are currently reviewing how they undertake this function, and as part of their review have commissioned this research project. The research study aims to provide an in-depth analysis of views from a diverse range of quality assurance partners and other organisations about the GMC's approach and framework for quality assuring medical education and training in the UK. Findings will inform the GMC's review of their approach to quality assurance, providing evidence by which they can advance their practices and processes in quality assurance.

3. Why have I been chosen?

We have identified that you work in a quality assurance role for an organisation that has direct experience of the GMC's quality assurance processes, or an organisation that has an approach to quality assurance that the GMC is keen to understand further. We believe that your expertise will offer valuable insight into what works well (and what doesn't) when assuring quality. We intend to talk with up to 40 individuals that represent a range of organisations involved in quality assuring medical education and training inside and outside of the UK, and more broadly outside of a healthcare context.

4. Do I have to take part?

Participation in the study is entirely voluntary and there will be no penalty or loss of benefits to which you are otherwise entitled if you decide to not participate. If you do decide to take part, you will be given this information sheet to keep for your records. You will also be asked to sign a consent form and to provide us with some contact information.

You can withdraw from the study at any time, without giving a reason and without prejudice. There will be no penalty or loss of benefits to which you are otherwise entitled if you withdraw. If you decide to withdraw you will be asked what you wish to happen to the data you have provided up that point.

5. What will happen to me if I take part?

Taking part in this study will involve a one to one interview with one member of the research team. Following the interview you may be contacted by the research team to discuss a case example in detail and clarify any points made during the interview. Beyond this, you will not be contacted to participate in future research. Interviews will take place via telephone but if you prefer face to face at your workplace then we will endeavour to accommodate. Interviews will last approximately 30-40minutes and you will be asked to discuss your thoughts on the GMC's approach to quality assurance and how their processes compare to that of your own organisations.

The last point that you are able to withdraw consent (and so the last point that the information you provide can be removed from the study) will be until the interim report due for submission on 29 June 2018.

6. Will I be recorded and how will the recorded media be used?

Interviews will be audio recorded and these recordings will be transcribed and anonymised. Access to audio recordings and transcriptions will be limited to UCL RDME team members and the professional transcription service used (who sign a confidentiality agreement). Interview recordings and transcripts will be stored securely by UCL RDME. The information provided will be used for analysis and small, anonymised sections may be used for illustration in conference presentations and journal articles. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings. Recordings and transcriptions will be destroyed after 5years.

7. What are the possible disadvantages and risks of taking part?

It is always possible that talking about your professional experiences may bring up issues that you find difficult or distressing. If this is the case, please contact Dr Ann Griffin a.griffin@ucl.ac.uk

8. What are the possible benefits of taking part?

Whilst there are no immediate benefits to participating in the project, it is an opportunity to share your organisation's good practice in quality assurance and to shape how the GMC improves on its current processes.

9. What if something goes wrong?

If something goes wrong and you wish to raise a complaint, you should inform someone straight away.

- If you wish to complain about your treatment by researchers please contact the project lead Dr Ann Griffin- a.griffin@ucl.ac.uk
- If you wish to alert us to something serious occurring during or following your participation in the project (e.g. a reportable serious adverse event) please contact Dr Ann Griffin- a.griffin@ucl.ac.uk

In the unlikely event that you should feel your complaint has not been handled to your satisfaction you can also contact the Chair of the UCL Research Ethics Committee – ethics@ucl.ac.uk

10. Will my taking part in this project be kept confidential?

All the information that we collect about you and your organisation during the course of the research will be kept strictly confidential. We will treat the data with the highest degrees of confidentiality. All data will be collected and stored in accordance with EU General Data Protection Regulation and kept on password-protected computers and, if necessary, encrypted memory sticks. Whilst we will refer to those organisations that have contributed to the research, the names of individual respondents will remain anonymous and confidential. The data you provide will be accessible only to the project research team and transcribers of the interviews. Interview data collected on electronic recording devices will be deleted after transcription.

11. Limits to confidentiality

Please note that confidentiality will be maintained as far as it is possible, unless during our conversation researchers hear anything that makes them worried that someone might be in danger of harm. In this situation, researchers might have to inform relevant agencies of this. To that end, confidentiality will be respected unless there are compelling and legitimate reasons for this to be breached. If this was the case we would inform you of any decisions that might limit your confidentiality.

12. What will happen to the results of the research project?

The results of this research project will be published in a report for the GMC. Some findings may also be published in academic journals and presented at conferences. Data may also be subject to secondary analysis which may also be published in academic journals and presented at conferences.

13. Who is organising and funding the research?

This research is funded by the General Medical Council but is being organised and conducted independently by UCL members of staff.

14. Contact for further information:

Project co-Investigators

Dr Paul Crampton, p.crampton@ucl.ac.uk

Dr Leila Mehdizadeh l.mehdizadeh@ucl.ac.uk

Research Department of Medical Education

UCL Medical School

Room GF/664



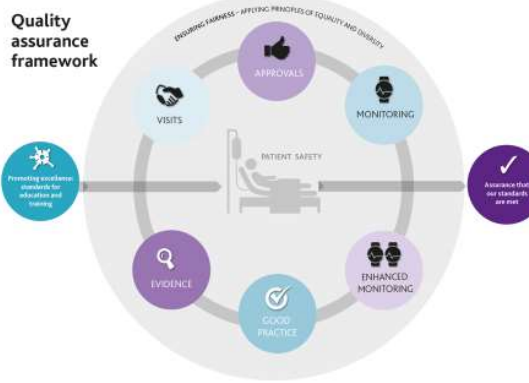
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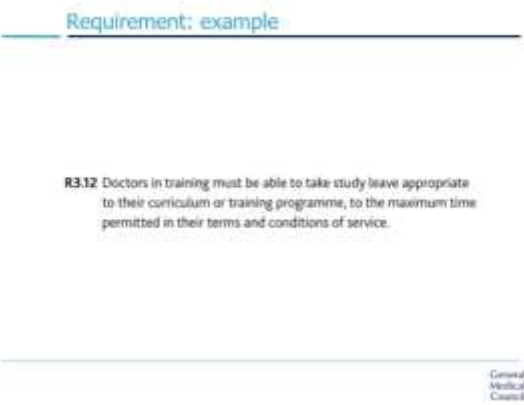

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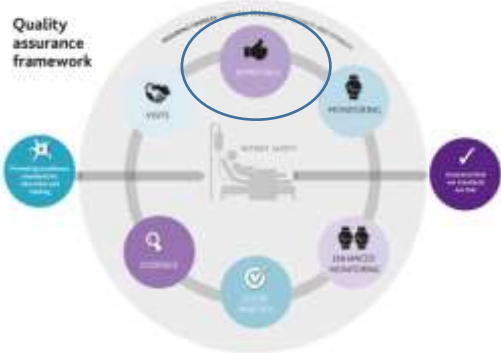

Thank you for reading this information sheet and for considering taking part in this research study.


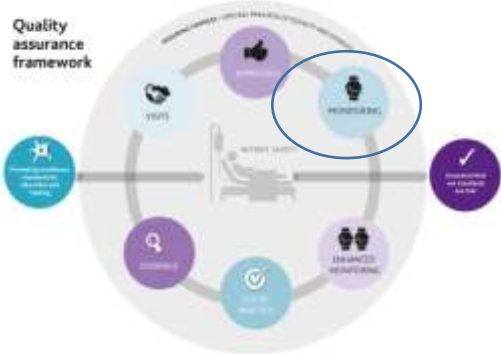
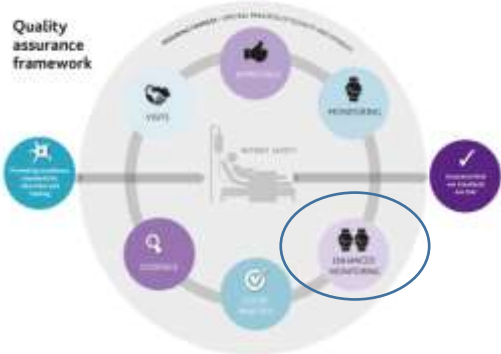
Video script

 <p>Quality Assurance</p> <p>General Medical Council</p> <p>Working with doctors Working for patients</p>	<p>Welcome to this short presentation about the General Medical Council's Quality Assurance framework.</p> <p>The General Medical Council (GMC) works to protect the public by setting, upholding and raising the standards of medical education and practice across the UK.</p> <p>One of its key roles is to make sure medical students and doctors get the education and training they need to deliver high-quality care throughout their careers.</p> <p>The GMC does this by setting standards for undergraduate and postgraduate medical education, and by undertaking quality assurance activities to ensure those standards are met. This includes asking organisations to self-assess against its standards; monitoring; and visiting organisations that manage education and training and training environments - including medical schools. It reports the findings on its website.</p> <p>The GMC also approves medical schools and postgraduate curricula, assessments, and training posts and programmes.</p> <p>This short video explains how the GMC does all this through its Quality Assurance Framework</p>
 <p>Quality assurance framework</p> <p>The diagram illustrates the Quality Assurance Framework as a circular process. At the center is a stethoscope. Surrounding it are several icons representing different stages: 'STANDARDS' (top), 'APPROVAL' (top-right), 'MONITORING' (right), 'ENHANCED MONITORING' (bottom-right), 'IMPROVEMENT' (bottom), 'ASSESSMENT' (bottom-left), and 'FEEDBACK' (left). A blue circle highlights the 'STANDARDS' icon.</p>	<p>This Quality Assurance Framework sets out how the GMC quality assures both undergraduate and postgraduate education and training.</p> <p>The GMC checks that standards are being met by approving all training programmes, posts, and locations. It then uses evidence to monitor these. When issues arise it can use enhanced monitoring to help resolve them.</p>

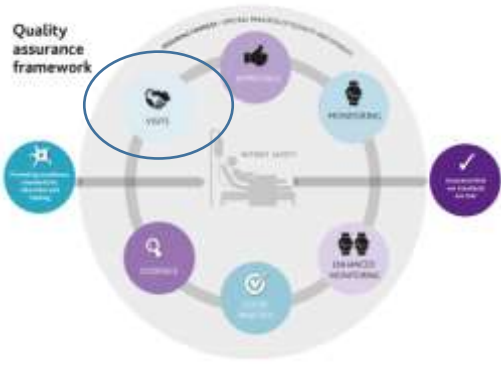
	<p>Underpinning all its quality assurance activities are quality standards.</p> <p>The GMC's standards for the management and delivery of undergraduate and postgraduate medical education and training are set out in <i>Promoting Excellence</i>.</p>
	<p>The GMC also sets the</p> <ul style="list-style-type: none"> • standards for the development and design of postgraduate medical curricula in <i>Excellence by Design</i>; • standards for medical students in <i>Outcomes for Graduates</i> and • standards for doctors in their first year of postgraduate training in <i>Outcomes for Provisionally registered doctors</i>.
	<p>For now though, we'll focus on the standards for undergraduate and postgraduate medical education and training.</p> <p><i>Promoting Excellence</i> is structured around five themes: Starting with theme 1 and moving clockwise, these are...</p> <ol style="list-style-type: none"> 1. learning environment and culture 2. educational governance and leadership 3. supporting learners 4. supporting educators and 5. developing and implementing curricula and assessments. <p>Patient safety is the GMC's first priority and, as you can see, is at the core of all its standards and requirements</p> <p>In each theme there are a number of standards and requirements setting out what an organisation must do to show that they are meeting the standards; some apply to a specific stage of education and training.</p> <p>Training organisations in the UK include medical</p>

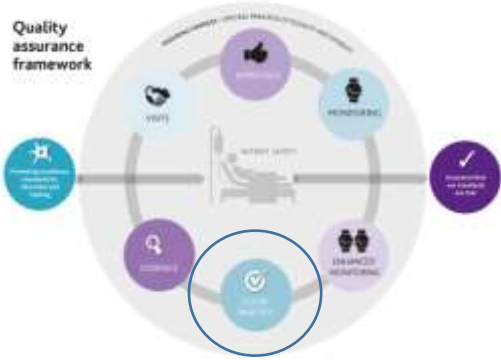
	<p>schools, postgraduate organisations such as deaneries and Health Education England, and local education providers (like hospital trusts and community healthcare settings).</p>
<p>Standard: example</p> 	<p>Here's an example of a standard, in the theme supporting learners:</p> <p>“Learners receive educational and pastoral support to be able to demonstrate what is expected in Good medical practice and to achieve the learning outcomes required by their curriculum”</p>
<p>Requirement: example</p> 	<p>And organisations must be able to show they meet this standard by addressing 16 requirements, including this one:</p> <p>“Doctors in training must be able to take study leave appropriate to their curriculum or training programme, to the maximum time permitted in their terms and conditions of service”</p>
	<p>The GMC works closely with other organisations to secure its standards, using this three-tier model.</p> <p>Tier one, the GMC, has an overarching responsibility to hold organisations to account for meeting its standards.</p> <p>The GMC quality assures the next tier: postgraduate training bodies and medical schools. These bodies hold a quality management role and organise, manage, commission, and sometimes deliver medical education and training. They must meet the GMC's standards in ensuring there are systems and processes in place to enable them to do this. They also manage quality in local education providers, where students and trainees are placed, such as trusts, health boards, GP</p>


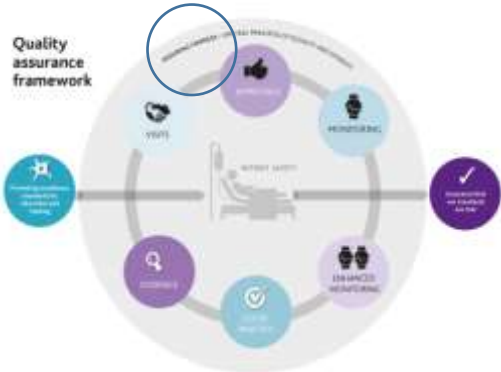
	<p>practices, and other clinical settings.</p> <p>These local education providers – the lower tier in the diagram - have quality control mechanisms in place to ensure good quality clinical placements and training posts and that their organisation provides a suitable learning environment. The GMC tests the relationships between organisations at every level as part of its overarching quality assurance.</p> <p>The medical royal colleges – on the right in the diagram - also engage with organisations at each tier. They work with the GMC to ensure their postgraduate curricula and assessments are fit for purpose, they inform specialty and programme delivery and have local systems in place to support training.</p>
 <p>The diagram shows a circular 'Quality assurance framework' with a central 'MEDICAL EDUCATION' icon. It is divided into four quadrants: 'LOCAL EDUCATION PROVIDERS' (top), 'MEDICAL ROYAL COLLEGES' (right), 'MEDICAL EDUCATION' (center), and 'GMC' (bottom). Various icons represent different aspects of the framework, including 'QUALITY CONTROL MECHANISMS' (top), 'EVIDENCE' (left), 'STANDARDS' (bottom), and 'REGULATION' (right). A blue circle highlights the 'QUALITY CONTROL MECHANISMS' icon.</p>	<p>The GMC also approves medical schools, postgraduate curricula designed by the medical royal colleges, regional training programmes, and the locations at which those programmes can be delivered.</p> <p>It also approves GP trainers and recognises trainers in specific roles in other specialties.</p>
 <p>The diagram is identical to the one above, but a blue circle highlights the 'EVIDENCE' icon on the left side of the framework.</p>	<p>The GMC takes an evidence-based approach to its quality assurance, including the approval of new schools and the ongoing assurance of training posts and programmes.</p>
<p>Evidence</p>	<p>It gathers, verifies and triangulates evidence from different sources which helps it to pinpoint areas of risk and good practice, spot patterns or trends, and ensure greater fairness.</p> <p>This shared intelligence helps the GMC to plan its quality assurance activities and make them more efficient</p>

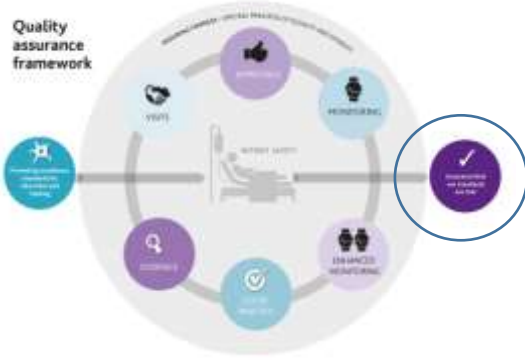

<p><u>Shared evidence</u></p> <p>helps us to:</p> <ul style="list-style-type: none"> • Identify areas of risk • Verify and triangulate • Identify trends or patterns • Ensure fairness. • Work proportionately with local providers • Plan our QA activity <p style="text-align: right;"><small>General Medical Council</small></p>	<p>It gathers evidence from a long list of sources, including its national training surveys of trainees and trainers, and outcomes of self-assessment undertaken by medical schools and postgraduate bodies.</p> <p>So for example, as well as evidence from visit reports, and reports and action plans from medical schools and postgraduate deans, the GMC looks at data on the outcomes of training programmes, and data from other audit and quality assurance bodies such as the Care Quality Commission.</p>
<p style="text-align: center;"></p> <p style="text-align: right;"><small>General Medical Council</small></p>	<p>Every year the GMC surveys all doctors in training and trainers for their views; that's close to 100,000 doctors.</p> <p>The survey asks doctors in training about the quality of their training and it asks trainers about the support <i>they</i> receive in their role.</p> <p>The results of the survey form a major part of the evidence base for the GMC, for postgraduate organisations and for local education and training providers.</p>
<p>Quality assurance framework</p>  <p>The diagram shows a central 'STUDENT LEARNING' icon surrounded by various quality assurance elements. One of the elements, 'PERSONNEL', is circled in blue.</p>	<p>The GMC also monitors the quality of training in regional programmes and locations through the deans' reports.</p> <p>Postgraduate organisations keep the GMC informed about any issues or risks arising in their area and there is frequent dialogue to discuss new evidence and developments.</p>
<p>Quality assurance framework</p>  <p>The diagram is identical to the previous one, but the 'STAFFING' element is circled in blue.</p>	<p>In certain circumstances, the GMC escalates to enhanced monitoring.</p>

<p><u>Enhanced monitoring</u></p> <p>Thresholds for escalation:</p> <ul style="list-style-type: none"> • Persistent and serious patient safety concerns • Students or doctors in training are put at risk • Students or doctors in training aren't getting the experience required by curriculum • Local QM processes are insufficient <p style="text-align: right;">General Medical Council</p>	<p>For example, if there are persistent and serious patient safety issues, students or doctors in training are put at risk or they are not getting the required experiences, the GMC will consider enhanced monitoring.</p>
<p><u>Enhanced monitoring</u></p>  <p style="text-align: right;">General Medical Council</p>	<p>This map shows enhanced monitoring by region. <i>(It's worth noting that this information alone doesn't necessarily reflect the quality of care or training in a region – for example one region may have more issues than others because of high quality reporting)</i></p> <p>The GMC publishes information about issues which are under enhanced monitoring. This promotes transparency, drives improvement and helps organisations to learn from each other</p> <p>A case is escalated to the GMC's Enhanced Monitoring process if local quality management processes are insufficient to drive improvement.</p> <p>It requires more frequent progress updates from those responsible for managing these concerns.</p> <p>If progress is not apparent, the GMC may take statutory action which means it can place conditions on approval or withdraw approval.</p> <p>Placing conditions means that it can define a restriction on the approval. For example, if there is limited supervision in a department overnight, the GMC can specify that trainees can not work there overnight.</p> <p>It can also withdraw approval for a post or programme at an approved location. This means that trainees in those posts or programmes can no longer be placed within that specific location.</p>

 <p>Quality assurance framework</p>	<p>Visits are flexible tools, designed to reflect local differences and targeted towards areas of identified risk.</p> <p>And the GMC uses a number of different types of visit in its QA work.</p>
<p>Visits and monitoring</p> <ul style="list-style-type: none"> • Regional reviews • Thematic reviews • National reviews • Checks • New/overseas medical schools & programmes <p>[Reveal each bullet point to match commentary]</p>	<p>From 2011-2018, the GMC undertook a programme of regional reviews which involved external scrutiny, including visits, of all aspects of the management and provision of undergraduate and postgraduate training programmes.</p> <p>Thematic reviews are focussed on a single subject area. These may involve visits, and may also be research-based. Thematic quality assurance will be bespoke and proportionate to the themes or risks identified. For example, the GMC has done a thematic review of bullying and undermining of doctors in training, as its evidence suggested that this was an emerging issue</p> <p>National reviews are part of the GMC’s thematic quality assurance. They are undertaken when it wants to consolidate its evidence in a specialty to examine a specific aspect of training, or consider how education and training in that specialty is delivered across the UK. National reviews may be research-orientated or include sampling of different types of education and training programmes or environments. For example, the GMC may do a national review of a small specialty such as paediatric surgery, as the numbers are too small to provide useful reports in its national training surveys.</p> <p>The GMC may also undertake targeted checks, which will be outside the cycle of regional reviews. It uses its evidence base to choose sites to visit in order to test specific areas that it wants to check. Checks are a useful tool to examine the effectiveness of the GMC Quality</p>

	<p>Assurance Framework as well as to monitor a specific area of interest when a regional visit is not imminent but concerns don't warrant enhanced monitoring. The GMC may conduct such checks to and with medical schools, Health Education England, deaneries or Local Education Providers to explore, for example, progress on agreed actions, or to further examine information that's being collected and analysed locally.</p> <p>Quality assurance of new and overseas medical schools and programmes, leads to accreditation so, in contrast, these occur according to a set schedule. The GMC undertakes frequent and scheduled visits to assure itself that new medical schools and programmes meet its standards, before they can award medical degrees to students.</p> <p>The GMC publishes all of its reports on the GMC website. These reports state which requirements, or recommendations (if any) organisations are required to make. These reports also highlight areas of good practice that the GMC found during its visit.</p>
 <p>The diagram, titled 'Quality assurance framework', shows a central 'REPORT DATE' with a clock icon. It is surrounded by several interconnected nodes: 'YR15', 'PERFORMANCE', 'IMPROVEMENT', 'EVIDENCE', 'RESOURCES', 'COMPLIANCE', and 'RISK'. A star icon is also present on the left side of the diagram.</p>	<p>The GMC's role is not just to identify and tackle <i>poor</i> practice. It also recognises the vital importance of identifying and sharing good practice in quality improvement.</p>
	<p>It's been using evidence and intelligence from various sources to identify practices that work</p>

<p><u>How we identify practices that work well</u></p> <ul style="list-style-type: none"> • Regular returns and reports • Visits • Evidence base (eg NTS) • Conferences and fora • Engagement with partner organisations <p>[Reveal each bullet point to match commentary]</p>	<p>well.</p> <p>For example :</p> <ul style="list-style-type: none"> • It uses regular returns from Local Education and Training Boards and deaneries, medical schools, and medical royal colleges and faculties to highlight innovations and areas that are working well • It proactively looks for areas that are worth sharing at its visits to organisations and institutions • It uses trend results from the National Training Survey (NTS) to pinpoint areas that are likely to have a positive training environment and/or culture. It's been exploring these areas with support from Local Education and Training Boards deaneries. • It looks out for innovative practices at conferences and forums • It often identifies good practice through regular meetings with other regulators, interest groups as well as royal colleagues and faculties.
<p><u>Case study publication</u></p> <ul style="list-style-type: none"> • Launch of our dedicated website section on sharing practices: ➢ Case study based ➢ Clear signposting for further detailed information 	<p>The GMC is formalising the way it shares best practice too.</p> <p>It has a dedicated area on the GMC website which will feature case studies showcasing areas that are working well. There is clear signposting for further detailed information linked to the cases</p>
	<p>The GMC's standards require training pathways to be fair and this principle is embedded throughout its quality assurance work.</p> <p>It's also undertaking a major piece of work with others to explore the root causes of differential attainment and how it might be addressed. .</p> <p>Differential attainment is the gap between attainment levels of different groups of doctors. It's an indicator that training and medical education may not be fair. This occurs across many professions, not just medicine. A variety of factors such as social, economic and psychological can affect performance.</p> <p>So the GMC is raising awareness of differential</p>

	<p>attainment amongst trainees and educators. It's also working to build confidence in the profession to have difficult conversations about differential attainment.</p>
 <p>The diagram, titled 'Quality assurance framework', shows a central 'STUDENT LEARNING' icon. Surrounding it are several interconnected icons: 'TEACHING', 'ASSESSMENT', 'EVIDENCE', 'STAFF', 'RESOURCES', 'EFFECTIVE LEARNING', 'EFFECTIVE TEACHING', and 'EFFECTIVE ASSESSMENT'. A purple circle with a checkmark and the text 'EFFECTIVE LEARNING' is highlighted with a blue border.</p>	<p>So, in summary, this Quality Assurance Framework sets out <i>how</i> the GMC quality assures both undergraduate and postgraduate education and training</p> <p>There is a focus on the learning environment and equality and fairness in training pathways.</p> <p>The framework, in highlighting the importance of shared evidence, also takes into account changes in relationships with other regulators such as Healthcare Inspectorate Wales and the Care Quality Commission. Regulators are making a real effort to work more closely together and to share information around emerging concerns in order to take collective action. This is a work in progress, but the direction of travel is very much to expand joint working with other regulators.</p> <p>The GMC draws on evidence from multiple sources. With more robust evidence, it aims for its visits and monitoring to be risk-based, proportionate and targeted.</p>
 <p>General Medical Council</p> <p>https://www.gmc-uk.org/education/how-we-quality-assure</p> <p>Working with doctors Working for patients</p>	<p>And finally, the GMC uses evidence to identify and share practices that are working well too.</p> <p>We hope you have found this introduction useful to understand the GMC's processes.</p> <p>If you want any further information, please go to the section called "<i>How we quality assure</i>" on the GMC website – the full link is here on the slide.</p> <p>Thanks for watching.</p>

Quality Assurance partners interview schedule

Structure

Introduce and duration about 45 mins

The aim of the study is to evaluate the effectiveness of the GMC's approach to quality assuring medical education. We are interested in your views of the GMC's Quality Assurance framework (QAF) and how it is applied in undergraduate and postgraduate education and training. This study will explore a range of stakeholder views, from organisations who have experienced the framework, like you. It will also explore the perspectives of other organisations, outside of medicine and healthcare, nationally and internationally, to get the fullest understanding of the QAF and how it might be developed.

We are keen to explore your views and there are no right or wrong answers to any of the questions. We have sent round a video, and the video's script in case that was easier for you to read, so you can review the breadth of the GMC's quality assurance framework. Don't worry if you haven't seen it or read it but you may wish to refer to the video script as we go through the questions.

Process

This interview will be recorded and analysed, looking for common themes that arise across the interviews.

Consent

A reminder that we will not personally name anyone who takes part in the study. Do you have any questions before we start the tape? Thank you for signing the consent form [or take verbal consent if required].

Introductory/ Background questions

- How long have you worked in your quality assurance role?
- Who else in your organisation works in a QA role?

General: GMC quality assurance framework overall

- Are there any aspects of GMC's quality assurance framework that you think are particularly effective, i.e. give you reassurance in their processes?
- Are there any aspects of the framework that you think are less effective or problematic in some way, i.e. do not assure you?

Focused: Specific aspects of GMC's quality assurance framework

I would now like to ask some questions about different components of the QA framework and be keen for you to share your experiences where relevant.

Standards

- Are the standards the right ones? Prompt any missing?
- Are the standards helpful or unhelpful in anyway?
- Has using the standards had any impact on your organisation?

Approvals

- What would be the advantages of making the GMC's approvals time limited?
- What would be the disadvantages of making the date GMC's approvals time limited?
- Do you think the GMC's approvals process is effective?

Monitoring

- Is the GMC monitoring the right evidence to assess your organisations performance?
- What sources of evidence do you think give the GMC the best insight into your organisation?
- What other areas could they/should they monitor?
- Does monitoring have any impact on your organisation? Prompt: Positive/negative
- Turning to enhanced monitoring, some people would say that the GMC are overstepping their remit when they require postgraduate organisations to report training programs and local education providers to them, what are your thoughts?

Sharing evidence

How effective is the GMC at sharing evidence with you?

- Is there evidence that could be shared more effectively and how would that benefit your organisation?
- Is there any evidence that you feel should not be shared, in particular with other healthcare regulators?

Self-assessment

The GMC requires annual self-assessment from the medical Royal colleges and medical schools but not the postgraduate organisations.

- Do you think self-assessment is a helpful process?
- Some hold the view that organisational self-assessment is not a reliable process, what do you think?
- Has the process of self-assessment resulted in any organisational change?

Visits

- What purpose do you think visits to organisations have?
 - Prompt: What makes a visit effective?
 - Prompt: What are the important areas that visits should include?
- Most regulators are moving away from cyclical or scheduled visiting, towards entirely risk-based systems, however many GMC stakeholders believe the cyclical visits have many benefits and should be retained. What do you think?
- What would happen if the GMC did no visiting?

Reporting

The GMC currently publishes long-form visit reports on its website, as well as information about enhanced monitoring cases, and data tools such as the NTS reporting tool and the progression reports.

- What do you think of the current QA reporting?

- Are there any negative consequences of reporting data on the website?
- Does your organisation use the reports in anyway?

Good practice

The GMC aim to identify good practice across medical schools and postgraduate bodies and then publish this on their website.

- Is this useful to your organisation?
 - Prompt: positive aspects v negative
- Have you adopted any areas of good practice yourself?
- Some people would say more resources should go into quality enhancement rather than accountability. What are your views?

Fairness

- How can the GMC quality assure fairness in medical education and training?

Sanctions

Sanctions mean withdrawing trainee doctors from the NHS or closing down medical schools which has a critical impact on healthcare.

- In the case of an underperforming training organisation that is currently failing to meet required standards what might be a proportionate sanction from the GMC that is not as extreme as withdrawing approval?
 - Prompts: The GMC visiting, publicly available rating scales, time bound approvals

Collective assurance

The GMC has committed to working more closely with other regulators to find efficiencies and reduce the regulatory burden on the service.

- What would be the advantages for your organisation in this approach?
- Would there be any disadvantages?
- Would sharing data enable the GMC to identify risk better?
- How practical would it be for your organisation to undertake joint visiting?
- Do you think the GMC's approach to QA is proportionate to the risks involved in medical education and training?
- Do you have any suggestions for improving the GMC's quality assurance processes?

Thank you for your time. Is there anything you would like to add that we haven't discussed?

Thank you

Quality Assurance non-partners interview schedule

Structure

Introduce and duration about 45 mins

The aim of the study is to evaluate the effectiveness of the GMC's approach to quality assuring medical education. We are interested in your views of the GMC's Quality Assurance framework (QAF) and how it is applied in undergraduate and postgraduate education and training. This study will explore a range of stakeholder views, from organisations who have experienced the framework. It will also explore the perspectives of other organisations, outside of medicine and healthcare, nationally and internationally, to get the fullest understanding of the QAF and how it might be developed.

We are keen to explore your views and there are no right or wrong answers to any of the questions. We have sent round a video, and the video's script in case that was easier for you to read, so you can review the breadth of the GMC's quality assurance framework. Don't worry if you haven't seen it or read it but you may wish to refer to the video script as we go through the questions.

Process

This interview will be recorded and analysed, looking for common themes that arise across the interviews.

Consent

A reminder that we will not personally name anyone who takes part in the study. Do you have any questions before we start the tape? Thank you for signing the consent form [or take verbal consent if required].

Introductory/ Background questions

- Can you briefly explain the context in which your organisation is involved in QA
- What is your specific role?
- How long have you worked in your quality assurance role?
- Who else in your organisation works in a QA role?

General: GMC quality assurance framework overall

- Are there any aspects of GMC's quality assurance framework that you think are particularly effective, i.e. give you reassurance in their processes?
- Are there any aspects of the framework that you think are less effective or problematic in some way, i.e. do not assure you?

Focused: Specific aspects of GMC's quality assurance framework

I would now like to ask some questions about different components of the QA framework and be keen for you to share your experiences where relevant.

Standards

- Are the standards the right ones?
 - Prompt: Any missing?
- Are the standards helpful or unhelpful in anyway?

Approvals

- Do you think the GMC's approvals process is effective?
- What would be the advantages of making the GMC's approvals time limited?
- What would be the disadvantages of making the date GMC's approvals time limited?

Monitoring

- Is the GMC monitoring the right evidence to assess organisational performance?
 - Prompt: What other areas could they/should they monitor?
- Do you think monitoring has any impact on organisation performance?
 - Prompt: Positive/negative
- Turning to enhanced monitoring, some people would say that the GMC are overstepping their remit when they require postgraduate organisations to report training programs and local education providers to them, what are your thoughts?
- How does your organisation use monitoring?
- Do you have a model for triangulating predicting risk?

Sharing evidence

- How could the GMC improve sharing its evidence?
- Prompt: Between regulator to regulator; between regulators to QA partners?
- Is there other evidence that could be shared?
- Prompt: Is there any evidence that you feel should not be shared?

Self-assessment

The GMC requires annual self-assessment from the medical Royal colleges and medical schools but not the postgraduate organisations.

- Do you think self-assessment is a helpful process?
- Some hold the view that self-assessment is not a reliable process, what do you think?
- What is your organisations approach to self-assessment?
- Has the process of self-assessment resulted in any organisational change?

Visits

- What purpose do you think visits to organisations have?
 - Prompt: What makes a visit effective?
 - Prompt: What impact do you think organisational visits have?
- Most regulators are moving away from cyclical or scheduled visiting, towards entirely risk-based systems, however many GMC stakeholders believe the cyclical visits have many benefits and should be retained. What do you think?
- How can visits give greater assurance of quality?
- What would happen if the GMC did no visiting?

Reporting

The GMC currently publishes long-form visit reports on its website, as well as information about enhanced monitoring cases, and data tools such as the NTS reporting tool and the progression reports.

- What do you think of the GMC approach to reporting?
- How does your organisation report on performance?
 - Prompts: strengths and weaknesses?

Good practice

The GMC aim to identify good practice across medical schools and postgraduate bodies and then publish this on their website.

- What do you think of the GMCs approach to sharing best practice?
- Some people would say more resources should go into quality enhancement rather than accountability. What are your views?
- What is your organisations approach to this?

Fairness

- How can the GMC quality assure fairness in medical education and training?

Sanctions

In the GMC's context, sanctions mean withdrawing trainee doctors from the NHS or closing down medical schools which has a critical impact on healthcare.

- Does your organisation have any advice or experience of imposing meaningful sanctions that would not be considered as extreme as the GMC's approach?

Collective assurance

The GMC has committed to working more closely with other regulators to find efficiencies and reduce the regulatory burden on the service.

- Is your organisation involved in joint visits? If so, what would be the advantages/ disadvantages for your organisation in this approach?
- Do you sharing data with other organisations?
- How practical would it be for your organisation to undertake joint visiting?
- Do you think the GMC's approach to QA is proportionate to the risks involved in medical education and training?
- Do you have any suggestions for improving the GMC's quality assurance processes?

Thank you for your time. Is there anything you would like to add that we haven't discussed?

Thank you