To consider

Standards work programme for 2014 and the oversight of guidance development work

Issue

1. Our plans for the Standards work programme for 2014, including our approach to internal oversight, external involvement, and resources for existing implementation projects.

Recommendations

2. The Strategy and Policy Board is asked to:

   a. Approve the Standards work programme for 2014.

   b. Approve the proposed model for ensuring internal oversight of the work of Task and Finish Groups and development of explanatory guidance.

   c. Approve the establishment of two Task and Finish Groups to engage external interests in the development of two major guidance development projects.

   d. Consider the future of implementation materials developed by Standards.
Standards work programme for 2014 and the oversight of guidance development work

Issue

The standards work programme for 2014

3 The Strategy and Policy Board is responsible for approving the standards and ethics work programme and any task and finish groups that are created to support it. As there were no new Standards projects in 2013, during which time we focused on the publication and promotion of the new edition of Good medical practice (GMP), and the Review of our Standards work, this is the first time the full standards work programme has been considered by the Board.

4 In drawing up the programme we have taken account of the Standards Review recommendations. A summary of the Standards Review report is at Annex A, and its recommendations are at Annex B.

5 The schedule showing key milestones and deliverables for the proposed work programme for 2014, at Annex C, consists of:

a Four GMC projects that will, or may, result in the publication of new guidance.

b Three external guidance development projects to which we are contributing.

c An internal collaborative project to promote good practice in the care of older people and care of the dying person.

d A business improvement project to achieve efficiencies in how we manage responses to requests for ethical advice, and extract wider benefits from this work.

e An indication of potentially significant demands on the Standards and Ethics team as a resource to help deliver other GMC programmes of work.

6 A summary of the drivers behind the guidance development projects, including reputational and other risks attached to the work is at Annex D.

7 The Standards team have agreed with the Strategy and Communication directorate that we can resource the work as it currently stands. However there are external influences within several of the projects, which mean that the timetable is not fully within our control, these are outlined in Annex B. These present delivery risks - approval of the programme would allow the Standards team to engage with external key interests on this.

8 We are also seeking approval:

a To establish an internal oversight arrangement for the guidance development work.
To establish two Task and Finish Groups.

To initiate work to agree arrangements for joint maintenance and development of guidance implementation resources.

Internal oversight of guidance development

9 In our governance model, the Strategy and Policy Board is responsible for overseeing guidance development and advising the Chief Executive. Guidance on core themes is likely to require Council approval.

10 Task and Finish groups are established to carry out the work of gathering and considering the evidence; recommending policy positions and draft guidance for consideration by the GMC. We have not yet developed guidance under this model, and we see a number of critical assurance activities that may not be fully covered.

11 We propose that during guidance development and drafting, a Task and Finish Group would be presented with a succession of questions about the policy positions to be adopted on possibly contentious points of principle; where to set the bar on matters where the law is silent or unclear; and how to proceed on issues where members cannot reach a consensus. In some cases a GMC policy steer may be needed within a short turnaround time, to inform Task and Finish Group drafting decisions. If the Board is unable to provide the deliberative space to address such issues, there appears to be a gap in our assurance process.

12 As the guidance has to work for all of our regulatory functions, we recommend that we establish a mechanism which involves other parts of the organisation as the guidance is developed.

13 We therefore propose setting up an internal group to oversee the work of the Task and Finish Groups, as well as smaller scale guidance development projects not led by Task and Finish Groups.

14 This oversight group would provide a steer to Task and Finish Groups, and provide assurance to the Board that guidance presented for its approval is robust and internally consistent.

15 The group would be made up of the Director of Education and Standards, and Assistant Directors from Standards, Education, Fitness to Practise and Strategy and Communication, the Senior Medical Advisor and possibly a Clinical Fellow. The group should also include a principal legal advisor to assess legal risks throughout (rather than at the end) of the process.

16 If agreed in principle we will develop terms of reference for the Board’s consideration and approval. It is likely that quarterly meetings would be sufficient.
External involvement in guidance development

17 Effective external engagement will continue to be essential for the credibility of the final guidance. For our major guidance, Task and Finish Groups provide a space for debate and external challenge and input from those working in clinical practice and those with particular interests.

18 However, Task and Finish Groups are resource intensive, and given the number of projects it would be unwieldy to establish a Task and Finish Group for each one. We therefore propose to establish two Task and Finish Groups for the major projects on confidentiality and private/cosmetic practice. A draft statement of purpose and outline membership of our Task and Finish Groups is at Annex E.

19 The other explanatory guidance projects do not warrant Task and Finish Groups, although they will require effective external input and buy-in. We propose that the internal oversight group should steer this work using ‘enhanced’ approaches to evidence gathering and engagement, through the Regional Liaison Service, Devolved Offices, and other externally facing teams, the Intelligence and Insight Unit, and collaboration with other regulators where possible. This would be a new approach and we should review its effectiveness within a reasonable timeframe.

The future of Standards implementation materials

20 We also need to be effective in promoting the guidance, getting key messages to doctors and patients, and helping to translate principles into practice.

21 We have a wide range of existing online resources and feedback is good (Annex F lists existing materials with data on their use) but we have not undertaken work on these materials since Spring 2013, while awaiting the outcome of the Standards Review.

22 There are some risks around not updating these materials in 2014; for example during the development of GMP 2013 we made undertakings to Mencap, GRES, GLADD and the EHRC to develop further GMPIA case studies, which we have not yet done. Failing to ‘retire’ older FtP cases and add new ones to GMP online may quickly reduce the value of this content. It will be helpful to further engagement with key interests if we can give some indication of our plans for 2014-2015.

23 The Standards Review concluded that guidance implementation work should be a collaboration between our Standards team and the Strategy and Communication directorate. We are already working successfully with this model in planning and funding joint resources and campaigns in 2014 to promote good practice in the care of older people and dying patients.
Supporting information

How this issue relates to the corporate strategy and business plan

24  This issue relates to Strategic Aim 2 of the Corporate Strategy and Business Plan: help raise standards in medical education and practice.

What equality and diversity considerations relate to this issue

25  We will undertake equality analyses throughout all our guidance development projects. Our engagement strategies will ensure we hear from diverse groups of patients, doctors and the public.

26  Our learning materials help doctors to provide care to all their patients, and highlight some of the challenges related to providing care to particular groups of patients, for example older people.

If you have any questions about this paper please contact: Martin Hart, Assistant Director - Education and Standards, MHart@gmc-uk.org, 020 7189 5408.
3 - Standards work programme for 2014 and oversight of guidance

Annex A

Report of the Standards Review

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Annexes [included in SPB papers for 22 February 2014]
Annex A: Timeline of GMC guidance on standards and ethics to 1995
Annex B: Table of guidance and supporting materials
Annex C: Postcard/online doctors survey
Annex D: Standards and Ethics Team activities
Annex E: Our standards and guidance work
Annex F: Criteria for decisions on guidance from the 2002 standards review
Annex H: Process for selecting and summarising/anonymising FtP determinations
Maintaining the standard: a review of the GMC’s standards and ethics work
1. Executive Summary

1. The purpose of this review was to consider our standards and guidance work in light of the development of a new corporate strategy and the publication of the new version of Good medical practice (GMP).

The review

2. Our aim is to produce guidance that is widely read, understood and respected by the medical profession, and that is regarded as relevant and helpful to all registered doctors. The development of the Corporate Strategy 2014-2017 provided us with an opportunity to look at how our standards and guidance work supports this aim, taking into account the changes that have taken place in the GMC’s work over the past few years.

3. The review has not considered the content of the guidance itself, but has looked at issues such as how we deliver the guidance, how much guidance we should produce and what issues we should cover. As such, it has principally been an internal exercise, and the review team engaged extensively with individuals and teams across the GMC.

4. We did however engage with a number of our key interest groups such as the British Medical Association (BMA), Medical Defence Union (MDU) and medical royal colleges to understand how they perceive and use the guidance. We engaged with patients, through an online poll, and with doctors, including through engagement at GMC Regional Liaison Service (RLS) events, and through an online and postcard survey. We also drew on the experience and insight of the National Medical Director’s Clinical Fellows.

5. We also met with other regulators both within and outside the healthcare environment to get a wider perspective on the challenges other regulators face and the approaches they take to meet them.

Key findings

How others see the guidance

6. The guidance is held in high regard and is considered to be authoritative. There is no case for changing the basic model of giving guidance, or the status of the guidance.

7. However, doctors do not read or refer to the guidance on a regular basis. Often, they turn to others – such as the defence associations and medical royal colleges – for ethical advice. In many cases these bodies base their advice on our guidance.

8. We should therefore not try to work alone to encourage doctors to work in line with our guidance. We are well respected but we can broaden our credibility by working with the organisations that doctors trust and turn to for advice.
How we use the guidance within the GMC

9 Our standards work is core to the work of our other functions. There does however seem to be considerable variation across the GMC in terms of familiarity with the content and status of the guidance, particularly the explanatory guidance, and its implications for professional practice.

10 There is also a tension between our power to give advice on good practice and our power to take action against registration. The difference between the standards we set and the specific thresholds for taking action against a doctor’s registration can be seen to create an ‘expectation gap’ where the public expect us to take action but we are not able to do so.

11 This means that patients, the public and doctors do not always understand when we will or will not take action. We could do more to help doctors and the public to understand our thresholds for taking action.

Raising professional standards

12 Developing guidance is only one of a number of possible regulatory interventions the GMC has at its disposal to help raise professional standards. The use of guidance as a response has to be weighed against the other levers for action the GMC has available.

13 We are moving towards a more explicit risk and intelligence model across our work and this needs to be reflected in our decisions about our guidance work. In the short term the Strategy and Policy Board should oversee the development of some criteria to help the organisation understand when guidance should be developed and reviewed.

14 We need to target our activities to promote professionalism more effectively and to be more intelligence-led in deciding where to act. This needs to be supported by high level agreement on priorities and the allocation of resources.

The governance of our standards and ethics work

15 Our governance model has changed, and decisions on our guidance need to adapt to these changes. We need to be clearer about how we make decisions to develop or revise guidance and learning materials.

16 We also need to find new ways of ensuring the continuing legitimacy and credibility of our guidance. The review sets out a number of options to do this.

Recommendations

The review sets out recommendations in four areas:

Operational delivery

- The basic model of the guidance is robust and the guidance should remain applicable to all doctors to the extent that it applies to their work.
We need to be clearer about the relationships between the different pieces of guidance.

We need greater clarity about the roles of the various teams responsible for implementing the guidance.

We should continue to provide advice in response to enquiries about the guidance, but the delivery model should be reviewed.

When the organisational structure of the GMC is next reviewed consideration should be given to the Standards and Ethics Team becoming part of a central function.

We should continue to use task and finish groups and ensure that consultation is proportionate to the issues.

**Dissemination of guidance**

- We should overhaul how we present the guidance on the website.
- We should develop the concept of a trusted partner to encourage others to provide context-specific guidance to groups of doctors based on our guidance.
- We should use our marketing knowledge and what we learn from audience profiling to target the delivery and presentation of our guidance.
- We need to recognise more openly the gap between what we describe as good practice and what we are able to take action on.

**Embedding our standards work internally**

- The role of the Standards and Ethics Team should be extended to include the development of an internal resource to provide training for staff on the nature and implications of our ethics and standards work.
- We should consider how we can further develop the culture of sharing policy ideas across the GMC.
- We should review the links to GMP in our guidance for decision makers in the early stages of our fitness to practise procedures.

**Making decisions on our guidance and other materials**

- We need to be more intelligence-led in making decisions about our guidance and develop criteria for when guidance is, and is not the right response.
- We should think more broadly about the range of tools and levers available to us in seeking to protect patients, especially when a rapid response is required.
- We should clarify how staff with responsibility for our standards and ethics work will be supported to make policy and operational decisions.
- We need high level agreement on our priorities and the allocation of our work to promote professionalism.
2. Background to the review

In recent years the GMC has taken on significant new areas of responsibility, including for postgraduate medical education and training. New services, such as the Regional Liaison Service (RLS) and the Employer Liaison Service (ELS), are changing the way we engage with those we regulate, and the relationship between the standards function and the other parts of our work has evolved.

The standards in *Good medical practice (GMP)* and the other ethical guidance inform all areas of our work. They underpin our processes for assessing doctors' fitness to practise, and provide the framework for education, appraisal and revalidation. Our ambition is that the standards and guidance should be relevant and helpful to all registered doctors and should be at the centre of a productive relationship with every doctor, which lasts throughout their career.

This review considers how our standards work can support this ambition and maintain the very high regard that our standards are held in as the GMC evolves and the environment it works in changes. It follows the launch of a new edition of *GMP* in the spring of last year.

**The process**

The issues under consideration have formed part of the discussion at the GMC for some time and a considerable amount of work and thinking has already been undertaken to support this debate. At the outset the review team undertook a detailed review of existing evidence about how doctors and others perceive and use the standards and guidance.

As part of the review process the team then engaged with:

- individuals and teams across our work
- a sample of our key interest groups such as the British Medical Association (BMA), Medical Defence Union (MDU) and the medical royal colleges
- other regulators both within and outside the healthcare environment
- doctors, including through engagement at RLS events and conferences, and through an online and postcard survey exploring where they go for advice on ethical matters
- patients, through an Ipsos MORI online poll asking about where they would get information on what to expect of their doctors.

3. About our guidance

This section explores the development of our guidance and its status. Our standards and guidance have evolved over many years. To understand how we have got to this point and to provide a record of this evolution we set out some of the history and the changes that have taken place.
Legal and historical context

Section 35 of the Medical Act 1983 (as amended) (the Act) provides the GMC with the power to ‘provide, in such a manner as the Council thinks fit, advice for members of the medical profession on standards of professional conduct; standards of professional performance; or medical ethics’.

This is a very broad provision, which we can use as a general power to give advice to the profession, as long as we act within general public law principles and other legal duties (for example in terms of fairness, reasonableness, rationality, and equality).

Over our history we have interpreted this power and its forerunners in different ways. Between 1968 and 1993 the GMC published guidance on professional standards in the form of the *Blue book*¹, a series of publications the chief purpose of which was to give guidance on the behaviour and conduct that would constitute serious professional misconduct (the so-called ‘five A’s’ – alcohol, adultery, abortion, association with unqualified doctors and advertising). A short timeline is at Annex A.

By the 1980s there was a growing sense of the need to express professionalism in positive rather than negative terms. The GMC (and others) needed to be able to answer the question: ‘What are the qualities of a good doctor?’ In 1988 the GMC issued the statement *HIV Infection and AIDS: The Ethical Considerations*. This heralded a change in approach with the focus shifting from the reputation and discipline of the profession to the rights and needs of patients.

The first edition of *GMP* followed in 1995 and represented a fundamental change in our approach to giving advice to doctors. It was no longer a list of things not to do but instead was a positive description of ‘good’ practice (not the highest possible standard, and not minimum standards), which should be attainable by everyone on the medical register and relevant to all doctors. The interests of patients (and not those of the profession) were placed at the centre of the new statement of professional values and standards.²

The initial intention had been for the description of good practice to be published alongside a revised version of the disciplinary manual. The revision of the *Blue book* was never undertaken however and *GMP* replaced it in 1995. Since 1995 our approach has evolved, with increasing emphasis on the importance of good practice and our role in supporting doctors with guidance on ethical issues.

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¹ All of these publications can be found in the ethical guidance archive on the GMC website: [http://www.gmc-uk.org/guidance/archive.asp](http://www.gmc-uk.org/guidance/archive.asp). Accessed 20 December 2013.

What we mean by ‘the guidance’

The guidance is:

- **GMP**, the ‘core’ guidance, which describes the principles and values that doctors are expected to apply in their practice. This is published in hard copy and available online.
- The explanatory guidance, which provides detail on how to apply the principles in *GMP* in practice. These divide into:
  - seven published booklets on core themes, which are published in hard copy and available online, and
  - 24 pieces of explanatory guidance, which provide more detailed explanation of the guidance in the booklets and which are available online only.

All of this material is collectively considered as ‘the guidance’. It all has the same formal status although in practice there is a perceived hierarchy (at least by the Standards and Ethics Team), as shown in Figure 1.

![Figure 1: the perceived hierarchy in the guidance.](image)

We have also developed a variety of supporting materials to help to illustrate how the principles in the guidance might apply in practice. These include interactive case studies (*GMP in action*); static case studies (published in pdf form on the relevant guidance page); the learning disabilities microsite; and decision making flowcharts. The supporting materials are not part of the guidance. A full list of guidance and supporting materials is at Annex B.

The status of the guidance

There are significant expectations, amongst both the medical profession and the public, about the role of our guidance and the impact it has on doctors’ practice. As we become
more outward facing we need to be clear amongst ourselves about the status of the guidance and how to explain it to a broader audience.

The Act gives the GMC the power to provide ‘advice’ to the medical profession. The guidance is therefore not binding: it is not a statutory code, or a set of rules, and there is no automatic link between breaching the guidance and action against a doctor’s registration.

The guidance is not merely advisory however. It sets out the standards of competence, care and conduct that the GMC expects of all doctors. Serious or persistent departure from the guidance will raise a question of whether a doctor is falling seriously short of the standards expected such that their fitness to practise might be impaired. We can take action against a doctor’s registration when this is the case.

Doctors are expected to be familiar with the guidance and to use their judgement in applying the principles to the situations they face in practice. They must be prepared to justify their decisions and actions.

The role of the guidance

The guidance applies to all registered doctors, whether or not they hold a licence to practise and regardless of their specialty, grade or area of work (for example, NHS or independent practice). The guidance is used for a number of purposes.

- It articulates the core values of medical professionalism. Without such guidance doctors and patients would have no fixed point of reference on issues such as respect for patient autonomy and dignity.
- It provides the framework for appraisal and revalidation.
- It sets out the core behaviours, knowledge and attitudes that inform the outcomes for undergraduate and postgraduate education and training.
- It provides a benchmark for considering complaints about doctors’ practice.

Above all the guidance represents an agreement between society and the medical profession about what is expected from doctors in our community. The guidance is based on established ethical principles such as autonomy, confidentiality, justice and consent, and represents common ground between doctors and patients in what are often very sensitive and potentially divisive areas of practice.

Increasingly we have recognised the public as a discrete audience for our guidance, with a growing expectation from patients in particular that the guidance will be relevant to their interaction with doctors. The recent publication of our guide for patients is a manifestation of this trend.³

4. What we learnt over the course of the review

How others see and use our guidance

The guidance is held in high regard

The GMC’s standards and guidance work, and *GMP* in particular, is well regarded in the UK and internationally. Courts and independent inquiries have commended the guidance and our activities to promote it:

‘*Good Medical Practice* is a sound basis from which to judge the fitness to practise of doctors... it sets out clearly, albeit at a relatively high level, the standards to be observed. It contains sufficient flexibility to cater for individual circumstances and preserves the independence of clinical judgement.’ (*Final Report of the Mid Staffordshire NHS Trust Public Inquiry*, vol 2)

The GMC continues... ‘to develop a broader understanding of professional obligation among doctors. ...we applaud the steps being taken by the GMC to encourage and support doctors to raise concerns when high professional standards are not met.’ (*Health Select Committee report - 2012 accountability hearing with the General Medical Council*, para 73)

Recently, the Supreme Court commented favourably on our end of life care guidance.4

The high regard for the guidance was also evident in the conversations and interviews we held as part of this review. While this evidence gathering was not comprehensive (and likely to be subject to some bias), we do not think there is a significant body of opinion that suggests that the standards themselves require a fundamental rethink.

The guidance is also considered to be authoritative. Government departments, medical defence associations, third sector organisations, the BMA, individual doctors and patients all turn to us for advice and we are frequently lobbied by others to link to their guidance from ours. It has also informed other regulators’ thinking when developing their own guidance and at least 14 countries are known to have directly translated *GMP* or our other ethical guidance, or used it as a model for developing their own national guidance.

Doctors don’t read or refer to the guidance on a regular basis

Previous research (for example, in 2010 an Ipsos MORI guidance survey5 and the follow up qualitative work6), soft intelligence gathered by the RLS, and our own postcard survey

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(Annex C) have found that most doctors are familiar with GMP but that awareness and use of the explanatory guidance are much lower.

Of course we are not alone in this. During this review we spoke to a number of other regulators, both within and outside of healthcare, and they told us that they are facing similar challenges with registrants’ awareness and use of their guidance. For example, the General Dental Council (GDC) spoke about the challenge of encouraging registrants to see its guidance as something that could be personally useful. The Solicitors Regulation Authority (SRA) shared its experience of moving from rules-based to outcomes-based regulation and the cultural shift for registrants (and the SRA) in moving away from ‘tickbox’ rules observance, and towards appraisal of risk and outcome.

Other regulators have experienced serious ‘guidance creep’ – for example, the Prudential Regulation Authority (PRA) described the difficulties that resulted from having vast volumes of guidance that it was not able to navigate. The PRA has therefore stepped away from providing material that explains the guidance or demonstrates what good practice looks like. Instead third party organisations (such as industry bodies) provide these materials.

Doctors do find our guidance helpful when they are aware of it – the Ipsos MORI survey found that nine out of ten doctors said so. And the RLS reports a significant demand for sessions provided by the service on our guidance. But the follow up qualitative work to the survey found that some doctors thought that the guidance was not sufficiently targeted to be relevant to daily practice. This was supported by some comments made during a perceptions audit conducted by the GMC:

‘The guidance is lovely but it’s in a bubble - it does not relate to real life.’

‘This is what is expected of me, but what if the systems and processes that I work within are not set up to enable me to do this?’

**Other organisations base their advice to doctors on our guidance**

In 2012 we carried out research to learn more about how doctors engage with guidance in general. Key findings included the following.

- Doctors favour guidance that is from a respected source, and is seen as relevant.
- Doctors use guidance that they can see has a direct and (preferably) quick benefit for themselves or for their patients.
- Information overload with limited reading time can prevent awareness and assimilation of published guidelines.

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We also know from anecdotal evidence, and from direct engagement, that doctors will often, understandably, turn first to another doctor working alongside them for advice and for support on difficult decisions.

In this review we explored these issues further in a postcard survey that asked doctors where they would turn for advice on ethical issues, other than to colleagues. Over 1,000 responded, and the majority (37%) put their medical defence association as the first choice. Employers were the second most popular choice (21%) and the GMC was third on the list (17%), above the medical royal colleges and the BMA. A fuller analysis of responses is at Annex C.

We know that the medical defence associations consult our guidance when giving advice. One of the defence associations told us that it viewed GMC guidance as ‘crucial’. The defence associations also provide 24-hour hotlines and can give more directive advice than we are able to.

Taken together, these findings suggest that we should not try to work alone to encourage doctors to work in line with our guidance. We are well respected but we can broaden our credibility by working with the organisations that doctors naturally turn to for advice. Doing this may help to offset the perception of the GMC as remote and lacking in understanding of ‘real-world’ day-to-day practice for doctors.

**How we use the guidance within the GMC**

*GMP is integral to the exercise of all our functions but there are inconsistent levels of awareness of the guidance across the GMC*

Our standards work is core to the work of our other functions. We cannot set standards in education, or decide upon admission or removal from the register, without an agreed description of what good practice looks like. We are increasingly aligning our regulatory functions to the framework of *GMP*. For example:

- The PLAB test is the main route by which International Medical Graduates demonstrate that they have the necessary skills and knowledge to practise medicine in the UK. These outcomes are mapped to *GMP*.
- The *Good medical practice framework for appraisal and revalidation* sets out the broad areas that should be covered in medical appraisal and on which recommendations to revalidate doctors will be based. The framework is drawn from *GMP*.
- The outcomes for F1 (provisionally registered) doctors are structured according to *GMP* and the standards for postgraduate training and assessment are embedded in *GMP*. *GMP* will also become central to generic professional capabilities as they develop.8

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There does however seem to be considerable variation across the GMC in terms of familiarity with the content and status of the guidance, particularly the explanatory guidance, and its implications for professional practice. The guidance has variously been described by colleagues during this review as ‘minimum standards’, ‘the gold standard’ and ‘our rules’, none of which is a correct understanding of its status.

**There may be differences in how thresholds are applied across our different functions**

A number of colleagues across the GMC have suggested to the review team that there may be differences in how thresholds are applied across our work. For example, the ‘five year rule’[^1], which applies in our fitness to practise procedures, does not apply at registration. This results in some difference in terms of how minor offences that are more than five years old are investigated at registration compared with how they are treated once the doctor is registered. Colleagues in the registration teams are currently considering these issues.

It has also been suggested that there may be some differences in how the test for impairment of fitness to practise is applied depending on whether the applicant has an entitlement to registration (the GMC has to prove impairment) or the decision to grant registration is at the discretion of the Registrar (the onus is on the applicant to satisfy the Registrar that fitness to practise is not impaired). These differences appear to be rooted in how the fitness to practise threshold has been operationalised in our registration processes (for example, we don't have powers to investigate health issues that arise prior to registration in the way that we do once a complaint is made about a registered doctor). These issues are outside the scope of this review but they do bear further consideration.

**There is a tension between our power to give advice on good practice and our power to take action against registration**

The relationship between the guidance and our fitness to practise procedures is complex for those not well versed in our processes. In the words of one of our legal advisers: ‘The key point is that standards guidance is not written to set thresholds for regulatory action. Its purpose is to describe good practice.’ Our fitness to practise processes have therefore evolved to incorporate consideration of the standards in the decision making process but the standards do not establish thresholds for deciding whether or not fitness to practise is impaired. That is a separate consideration, taken in the public interest.

We can take action against a doctor’s registration in the public interest where it appears that a doctor’s fitness to practise may be impaired by reason of misconduct, deficient...
The complexity in the relationship between the guidance and our fitness to practise decision making means that an ‘expectation’ gap has arisen

The difference between the standards we set and the specific thresholds for taking action against a doctor’s registration can be seen to create an ‘expectation gap’. Patients, the public and doctors don’t always understand when we will or won’t take action.

There is no single view amongst our key interests. Previous research has found that patient thresholds for regulatory action are lower than that of doctors and internal research to support our perception work found that members of the public were more likely to consider a failure by a doctor to be ‘serious’ or ‘very serious’ than another doctor would in three out of four scenarios. Members of the public were more likely to complain in all of the given scenarios. Anecdotally, doctors also complain that the thresholds for regulatory action are not clear.

It is also the case that breaches of some parts of the standards guidance are considered to be more serious than others, although that is not explicit in the guidance itself. For example, we take a more severe view of dishonesty or sexually inappropriate behaviour than we do of poor communication skills or failure to respect patients' dignity. Whether or not we pursue cases is also dependent on the extent to which we can establish clear evidence. This can be seen in *SOMEP* (2013), which reports that complaints about clinical care, or about clinical care combined with issues around communication, are less likely to meet the threshold for investigation than complaints concerning probity or the health of a doctor. We also know that 80% of complaints made by the public are closed without investigation.

There are good reasons for these differences. For example, it might be expected that complaints from a person acting in the public interest might progress further through our processes. But we could do more to help doctors and the public to understand our thresholds for taking action.

### How we organise ourselves

Over the past few years the GMC has undergone some fundamental changes to the way it works. At a very simple level both the volume and the complexity of our work have increased significantly with a consequential increase in our staffing and resource requirement. New services have been introduced, and we are seeking to be more influential with the medical profession and within public debate more generally. These changes have altered the relationship between the Standards and Ethics Team and other parts of the organisation. This section explores some of the key changes and how the Standards and Ethics Team and wider organisation might adapt to them.

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Our governance has changed, but decisions on our guidance have not caught up with the changes

The shift away from the Council’s engagement in executive decision making at the beginning of 2013 was a deep change in terms of how we make decisions. The change reflected the Government’s policy aim of simplifying governance arrangements, and creating smaller and more ‘board-like’ structures.\(^\text{15}\) Also, as our role evolved, and the complexity of our work increased, the previous model might have struggled to cope.

For the Standards and Ethics Team the change was acutely felt. The former Standards and Ethics Committee (SEC) provided a level of structure around agreeing a work programme and the content of our standards. The SEC also provided a standing forum for detailed debate on GMC policy positions on standards and ethics and gave direction on policy matters that did not need board-level consideration. This is now delegated to the senior staff.

While there is a clear recognition of the weaknesses as well as the strengths of the previous model this review has identified continuing uncertainty on a number of points, including:

- What are the criteria for decisions on whether to produce/revise guidance, or give some other response?
- Who will make these decisions/oversee the development process?
- Who will provide the expert medical and ethical input into the process?

A post-implementation review of the new governance arrangements will be carried out later this year, but this review has proposed some answers to these questions.

We are moving towards a more explicit risk and intelligence model across our work

Until last year, all proposals for new guidance or learning materials were formulated by the SEC and agreed by Council. The Standards and Ethics Team generated and analysed the evidence to support a proposal and members of the SEC also contributed their own knowledge and insights.

This was not a bad model. We were often successful at anticipating the direction of travel (for example, the review of our guidance on raising concerns anticipated the recommendations of the Francis report) and innovative (for example, with the creation of

GMP in action). But with the change of governance we need to find new ways of deciding where to put our efforts.

The recently established patient safety intelligence forum is expected to play an important part in this. As the forum is established, with support from units such as the Intelligence and Insight Unit centrally and the specialist teams within directorates, it will be in a position to direct the GMC’s regulatory activity. This should include advising when it is appropriate to develop or amend guidance. It should also be in a position to advise when another form of action might be more appropriate.

The role of the Standards and Ethics Team needs to be more clearly defined

This review found that the role of the Standards and Ethics Team is not well understood across the GMC. It is generally recognised that the team develops and revises guidance and learning materials, and provides advice about the guidance, but this is only a proportion of its work. A substantial amount of the team’s time is spent influencing the environment to support ethical practice (for example, responding to requests for advice from other organisations such as the departments of health; providing content for responses to consultations, select committees and official inquiries; and engaging with external groups). A full description of the team’s activities is given at Annex D.

Demands on the team – from within the GMC and from the wider healthcare environment – have grown as the organisation has moved towards a greater outward focus. At the moment, requests for the team’s involvement in projects are not well coordinated and tend to be made through bilateral arrangements.

Our changing focus has also meant that our standards and ethics work is now much broader than the Standards and Ethics Team. A wide range of teams are involved in promoting and embedding our standards and we are no longer clear about who is responsible for what. In particular there has been confusion about the extent to which the team seeks to lead on the implementation of guidance and how they relate to teams, particularly in strategy and communication, who are seeking to influence doctors’ practice.
5. Recommendations

This report sets out recommendations across three areas:

- The guidance and the role of the team
- Raising professional standards
- The governance of our standards and ethics work.

Earlier recommendations in the report relate directly to the standards function and the guidance itself. Later recommendations are of more interest to the wider organisation and have wider implications for the GMC’s work.

The guidance and the role of the team

This section considers the current model of the guidance and the role of the Standards and Ethics Team.

**We should continue to give guidance on professional standards and ethics and the status of GMP should not change**

As part of this review we considered the guidance from first principles, and asked whether we should continue to give guidance on professional standards and ethics. There is a strong consensus that the GMC should continue to do this. It is a fundamental part of the regulator’s role and, in its consultation on the future regulation of healthcare professionals, the Law Commission has proposed that it should be a duty and not a power.¹⁶

This review has also considered whether the core statement of professional values (currently GMP) should change from advice to something more binding, such as a statutory code. This could bring greater clarity about what will/won’t lead to action on registration, addressing the ‘expectation gap’.

This would however be a return to the ‘blue book’ approach of focusing on poor rather than good medical practice. It would be likely to undermine the impact of positive statements of professionalism and would be out of step with our ambition to raise standards of medical practice. There is also no suggestion that we are unable to pursue fitness to practise cases because the guidance provides an inadequate basis for doing so. GMP is sufficient to the needs of our fitness to practise procedures and provides sufficient flexibility for taking action in the public interest.

Recommendation 1: There is no case at present for changing our core approach to giving guidance on professional standards and ethics.

The guidance should apply to all doctors

The review has also considered the extent to which we should develop specific guidance that is targeted at sections of the profession but has concluded against this. The guidance, as an entity, has a particular status and weight. It is important to be clear about what does and doesn’t have the status of GMC guidance because of the role it plays in setting expectations about the conduct of doctors.

Of course not all of the guidance will be relevant to all doctors all of the time, but we should not try to define when it will or won’t apply. If we were to do this we would risk causing confusion about what guidance applied in a given case, with added complexity for fitness to practise hearings. A case examiner also argued that, given the diversity of modern medical careers, it would be very difficult to tailor guidance in a meaningful way.

Similar arguments apply to the question of whether we should target guidance according to where in the UK a doctor is working. While it is clear that the four countries of the UK are increasingly divergent in terms of the health and social care structures in which doctors work, and in terms of the legal frameworks in which they operate, there is agreement that the core principles that apply to doctors’ professional practice remain consistent across the UK. The relationship between the Standards and Ethics Team and the Devolved Offices in terms of identifying differences that need to be taken into account has also worked well to date. There is therefore no argument, under the current constitutional settlement, for creating different standards of practice.

There is however strong support for more effective targeting of our communications about the guidance to our different audiences, and for tailoring products such as case studies and other learning materials so that they more accurately reflect the issues that doctors face in practice. This is considered further below.

Recommendation 2: All of the guidance should remain applicable to all doctors to the extent that it applies to their work.

The model of the guidance is robust

The value of a core statement that sets high-level principles is that it is flexible enough to apply to all doctors, working in all circumstances, across the UK. More specific detail can then be given in explanatory guidance.

We do however need to manage the volume of the explanatory guidance, especially as all of it is potentially relevant to doctors’ fitness to practise. For example, the seven pieces of explanatory guidance that show how the principles of confidentiality apply in practice might be more effective as flowcharts or other kinds of supporting material. Getting this right is dependent on having a set of agreed criteria for when we should produce guidance, and for when we should produce something else. This is considered further in recommendation 11 below.

Confusion has also been expressed about whether the explanatory guidance establishes new principles. In theory it doesn’t – it expands upon high-level principles established in GMP, Consent and Confidentiality – but in practice it is not always clear that this is the case. This is particularly important where we are saying that a doctor ‘must’ rather than ‘should’ behave in a certain way. The model adopted in the 2013 explanatory guidance (which sets out at the beginning of the guidance which paragraphs of GMP, Consent or Confidentiality the guidance expands upon) is very helpful in this respect and should be continued in future explanatory guidance publications.

The relationships between the different pieces of guidance also need to be made clearer. The format of separate statements of explanatory guidance leads to some overlap of topics and it can be difficult to find the right piece of advice. Staff in the contact centre have found the guidance very difficult to navigate since the loss of the A to Z index during the launch of the new GMP web pages in April 2013. The MDU – one of the key users of the guidance on a daily basis – has also told us that it is having difficulty finding its way around the explanatory guidance.

It is beyond the scope of this review to set out a plan as to how the guidance should be organised in future but it is clear that work is needed to help readers to navigate it more easily. The design should be driven by an understanding of the needs of users of the guidance (for example, through audience segmentation and user testing) and should provide multiple routes for accessing the guidance. The opportunities offered by new technologies (such as apps) should continue to be explored.

Redesigning the presentation of the guidance would be a substantial piece of work that would require investment and the involvement of teams from across the GMC. But this needs to be weighed against the opportunities to influence doctors’ practice that are lost if our key audiences are not able to navigate our guidance. Work is under way on a new website that provides an opportunity to take this work forward.

**Recommendation 3: We need a fundamental overhaul of how we organise and present the guidance. In the short term:**

- The A to Z index should be restored as a priority.
- The structure of the explanatory guidance page should be reviewed to find ways of helping the reader to find what they are looking for.
**Recommendation 4:** In all new or revised explanatory guidance its relationship with the high-level principles in the core guidance should be explicit.

We need to be clearer about the role and responsibilities of the Standards and Ethics Team

The Standards and Ethics Team has a very particular body of expertise. This includes:

- understanding and being able to apply relevant legal and ethical principles to complex or controversial aspects of healthcare practice
- holding the repository of historical knowledge – how we got to current policy positions in the guidance (and why we don’t say something else)
- managing the process of developing guidance in a way that is open, inclusive, fair, transparent and consistent with national standards of good consultation practice
- drafting guidance to a standard that delivers the nuances required to meet the policy aim without straying outside the legal framework, while maintaining plain English standards.

This expertise underpins our ability to develop guidance on, and to comment in detail on, matters of professional standards and ethics. It is important that we protect this resource.

We also need to be much clearer about what is, and isn’t, the responsibility of the Standards and Ethics Team. For example, over the past few years the team has been increasingly called on to develop learning materials. These materials are becoming more important to our work but to be successful they need to be the responsibility of the teams that are closer to the end users, but that can draw on the skills and advice of the Standards and Ethics Team.

While it is not likely to be possible to create a definitive list of core activities, it is possible to describe some criteria that should govern decisions about the Standards and Ethics Team’s role. The need for the team’s involvement will vary according to:

- the extent to which a piece of work requires the team’s particular expertise
- the risk associated with getting something wrong, and
- the competence and confidence of others outside the team.

A full consideration of where the boundaries of responsibilities should lie is given at Annex E and summarised in the recommendations below. Further thoughts and recommendations on the relationship between the Standards and Ethics Team and other teams within the GMC are set out below.

**Recommendation 5:** We need cross-organisational agreement that the focus of the Standards and Ethics Team’s work should be:

- the development and revision of guidance
- the development of the content of learning materials (but not the development of the overall product, which should sit with the Strategy and Communication Directorate)
provision of complex advice

support of internal training on standards and ethics issues (see recommendation 7 below)

external engagement on issues where expert knowledge of the guidance is needed.

New models of engagement have created additional demands on the Standards and Ethics Team which it has struggled to meet

Over the past few years the GMC has evolved the way it engages with its key interest groups. The introduction of our liaison services is a significant step forward in this evolution. These services provide opportunities for us to engage face to face with doctors and others on professional standards in a way never possible before.

These changes have generated additional demands on, and expectations of, the Standards and Ethics Team, which it is struggling to meet. These have included enquiries about ethical issues, requests for presentational material and suggestions for new learning resources.

The team’s main strength over many years has been the development of guidance and advice. This is reflected in the description of the team’s work (see recommendation 5). In recent years the team has also delivered some significant products such as GMP in action to support the implementation of guidance. But whilst there have been some changes in the team to help manage this process and build expertise, the resources in the team are not going to be sufficient to meet the potential demand.

As our engagement grows, and we expand our ambition to promote professionalism, externally facing functions such as our liaison services will need to take the lead in developing the materials to support the implementation of guidance. They will also need to ensure that there are adequate resources in place, including corporate communication support and IS capacity, to support this work.

The advantage of this approach is that it ensures that the teams closer to the delivery of the material are able to tailor products to the audience whilst drawing on the unique competence of the Standards and Ethics Team in advising on content. It will free up the Standards and Ethics Team to concentrate on what it does best.

Recommendation 6: Responsibility for implementation of guidance should not rest with the Standards and Ethics Team. The team should advise on content to ensure that the integrity of our guidance is maintained.

In the short term the Standards and Ethics Team and RLS should together review the RLS’s immediate work plan to identify existing commitments that might require support from the Standards and Ethics Team and agree the support that the Standards and Ethics Team can provide.
We need to invest in the development of knowledge about our guidance outside the Standards and Ethics Team

Given the range of teams who use our standards and ethics guidance – either in decision making, in the formation of GMC policy relating to our other statutory functions, or in implementing the guidance – it is not realistic to expect the Standards and Ethics Team to provide quality assurance for all our activities. As set out above there is inconsistent knowledge across the GMC about our standards and guidance.

We therefore need to be sure that staff across the GMC have sufficient knowledge of the guidance to carry out their roles effectively, and that they also recognise the limits of their knowledge, and the risks associated with giving the wrong advice. The Standards and Ethics Team itself faces some short-term challenges in this area. As a result of a number of staff departures it will need to consolidate and grow its own knowledge and skills in 2014. The Standards and Ethics Team provides some training for other parts of the organisation on how the standards and ethics guidance relates to their work but this is on an ad hoc basis and has not been built into the team’s work programme. Capacity limitations have also meant that some recent requests for training (for example, from the Fitness to Practise Directorate) have not been met. And the team are not in a position to draw on good practice in the development of learning materials.

There is clearly a role for the team in developing the content for training of GMC staff. Either members of the team could deliver this training direct to others in the organisation (using a ‘train the trainer’ model) or external trainers could deliver it. Either way, a significant investment of the team’s resource would be needed to develop materials and this should be considered as a new role for the team and resourced accordingly.

The team should also continue to involve staff members from across the GMC in their work where possible to build understanding of the guidance and the context in which it is used. A recent successful initiative has been the involvement of colleagues from across the Education and Standards Directorate in discussions of ethical enquiries. Involving colleagues from across the GMC as new policy develops – for example, by holding policy update sessions – helps to build a richer engagement with, and understanding of, the detail of the guidance. This is particularly important for those who have a role in identifying audiences and communicating the guidance outside of the GMC.

Recommendation 7: The role of the Standards and Ethics Team should be extended to include the development of a new internal training resource. This could be through partnering with an external training company, or employing staff with experience of developing and delivering relevant training programmes, or another model.

In the short term we need to recognise that the resource available to the Standards and Ethics Team to provide training to others is very limited. The creation of such capacity should be prioritised.
We should review how we provide advice to individual doctors

The Standards and Ethics Team receives around 40-70 written and telephone enquiries on standards and ethics issues each month (other teams, including the contact centre, also answer ethical enquiries so the true number received by the GMC is higher). These enquiries come from individuals, from organisations (such as the BMA, or departments of health) and from any of our stakeholder groups. They can be one-off queries about discrete issues, requests from organisations to comment on their policies and guidance, and everything in between.

Response times vary greatly according to the urgency and complexity of the enquiry and the need for the adviser/drafter to conduct research, or seek advice from others, or obtain more senior sign-off for the response. The service level agreement for a response is ten days, although in recent months this has been extended to 21 days due to resource constraints in the team.

Providing this service places a significant demand on the team. Typically a straightforward question about our likely position on an issue can take a couple of hours (to carry out research, and to take advice); a complex or controversial issue may take several days if senior level input is needed; and a consultation response may take several weeks if input from other GMC teams is required.

It is unlikely that we would ever be able to stop giving advice on our guidance. As the body setting standards for doctors our stakeholders have a legitimate expectation that we will be available to explain the guidance, and help to apply the principles in practice. There are also significant benefits to the GMC of providing the service. For example, enquiries provide a useful source of intelligence about the wider healthcare environment, which informs our guidance development. They also provide opportunities for team members to develop their understanding of the guidance and how it applies in context.

We do however need to review the delivery service model and clarify the scope and ambition of the service. The Standards and Ethics Team has just initiated an ethical enquiries business improvement project to identify ways to maximise the efficiency and effectiveness of the process. As part of this review, the costs and benefits of providing this service should be identified, and the demand for ethical advice and compliance with SLAs should also be tracked to identify the impact on resources and provide operational management with clearer information on which to base decisions.

The team working on this project should also seek agreement from the senior management team as to the scope and ambition of the service. For example:

- What the timescales for responding should be (and whether these should vary for different categories of enquiry). Other organisations (such as the defence associations) offer a 24-hour service – what is our ambition?

- The sorts of enquiry that are within the scope of the GMC to answer (and when we should signpost the enquirer to other bodies, such as the defence associations).

- Criteria for when the expertise of the Standards and Ethics Team is needed (and when other parts of the GMC can manage the enquiry effectively).
How we ensure consistency across the GMC in responding to enquiries on standards and ethics. For example, the Education teams tend not to answer enquiries from individual students, whereas the Standards and Ethics Team does.

**Recommendation 8: We should continue to provide advice on our standards and ethics guidance but the delivery model should be reviewed.** The team working on the ethical enquiries business improvement project should consider what it can draw from this report to support its work. In particular the team should consider the costs and benefits of providing the advice service.

**The centrality of our standards work should be reflected in our organisational structure**

Our standards work differs from all other policy work carried out in the GMC in that it is not policy relating to how we deliver a statutory function – it is a statutory function in its own right.

Our standards work is core to all of our other functions. We cannot set standards in education, or decide upon admission or removal from the register, without an agreed description of what good practice looks like. This relationship is shown well in an image created by the RLS to explain our statutory functions:

The movement of the Standards and Ethics Team around the organisation (the team has moved five times since the first edition of *GMP* in 1995) shows that it has a relationship with all of our directorates. But it also shows that the team does not fit particularly well with any one directorate. One of the positive consequences of co-location (most recently with our fitness to practise and education functions) has been that it enriches the host function’s engagement with the guidance, and facilitates access to the team. But the downside is that it can distort the team’s engagement with other functions of the GMC by overemphasising one particular relationship.

Another consequence is that our standards work has never been the sole (or main) focus of any of our directors. In part this may be because the risks posed by our standards work (for
example, in terms of legal challenges to the guidance, which take years to play out) tend not to be as immediate as those posed by immediate operational decisions.

Some have argued that the standards and ethics function should be established as a directorate in its own right to reflect its status as a discrete statutory function. That is one option. An alternative is to establish the Standards and Ethics Team as part of a central function with clear lines for engaging with all of our directorates.

We also need to reconsider how all policy teams across the GMC work with each other. Currently engagements between teams tend to be done in relation to a specific issue, and often on a bilateral basis. Policy teams from across the organisation tend not to come together at an operational (rather than senior) level to share policy ideas. The consequence of this is that projects can develop in one part of the organisation that have impacts (or create opportunities) for other parts of the GMC, which are not recognised until the proposal is well developed and being discussed at board level.

**Recommendation 9:** When the organisational structure of the GMC is next considered, perhaps linked to the appointment of a new Chief Operating Officer, consideration should be given to the Standards and Ethics Team becoming part of a central function that has the experience of managing relationships across the organisation.

**Recommendation 10:** We should consider how we can develop the culture of sharing policy ideas across the GMC, coordinated by the Strategy and Communication Directorate.

**Raising professional standards**

Over the past few years the GMC has striven to become a more outward-facing and proactive regulator, and to be less reactive. But, as a national regulator and leading voice in healthcare, it is inevitable that we will be called upon to respond to issues affecting the sector. To do this effectively, we need to be clear about what we can and should do, what our range of responses is, and what is for others to do.

**Developing guidance should be seen as one tool amongst a range of possible regulatory interventions**

When issues arise in relation to doctors’ practice, there is often a call for us to issue new guidance, or to amend existing guidance. Recent examples include the public debate about abortion and sex selection, and face veils.

Producing new guidance is a very powerful response. It is also very resource intensive and time-consuming. The legitimacy and credibility of our guidance are dependent on having a development process that is well informed and transparent. Amending guidance that we have already issued without further consultation also brings risks of challenge on grounds of process, or counter-claims for amendment.
We also need to be careful not to produce too much guidance, which is a problem that other regulators have told us they face. The risk is that too much guidance dilutes the impact of the existing material or confuses both the internal users and the external audience.

Guidance should therefore only be the chosen route when it is the right response and there are no other more appropriate responses at our disposal. In most cases where guidance is not the right response, this will be because the issue:

- is already covered in existing guidance
- can be resolved by applying the principles in existing guidance
- needs an urgent answer that doesn’t allow for a lengthy development/consultation process
- is too specific (to one specialty/area/group of doctors) to justify guidance applicable to all registered medical practitioners
- falls outside the GMC’s remit.

Criteria for deciding whether or not to give guidance were agreed in the last standards review in 2002, but have not been consistently followed. These are given at Annex F. A comparable set of criteria should be developed and agreed by the Strategy and Policy Board to inform decisions in future.

We also need to develop criteria for reviewing and amending existing guidance. The legal and policy environment changes over time. Doctors and others rely on our guidance and so it is important that it remains compatible with the law and relevant to practice. Reviewing guidance on a scheduled basis allows issues to be considered in the round, with all key interest groups having the opportunity to contribute to the debate. Having a timetable for review also helps to manage the expectations of groups lobbying for amendments on specific issues as they can predict when they will next be able to influence our position.

Issues do however arise between scheduled reviews that might call into question the reliability, relevance or lawfulness of the guidance. Examples include new legislation that changes the scope of doctors’ duties, or a major change in how healthcare services are delivered. And as our knowledge develops and the medical profession changes we learn more about where Doctors need support to help them avoid harming patients or and provide better care. Increasingly we are becoming a more proactive body using soft and hard data to steer our work.

This approach needs to be accelerated in the directing our standards and guidance work. We need to move towards an intelligence led approach in this area. Working with teams such as the Intelligence and Insight unit and through the new Patient Risk Forum, the GMC needs to be much clearer where a risk to patient safety might exist and when it is appropriate to develop or amend guidance to help alleviate that risk.
Recommendation 11: We need to be much more intelligence led in making decision that about our guidance.

In the short term we should develop criteria for when guidance is, and isn’t, the right response, which should be agreed by the Strategy and Policy Board. A schedule for reviewing existing guidance, and criteria for reviewing guidance outside of the normal schedule, should also be developed and agreed with the Strategy and Policy Board.

The use of guidance as a response has to be weighed against the other levers for action the GMC has at its disposal

We have a whole range of responses that we can (and do) deploy to protect patients. As our responsibilities have grown, and our relationship with the environments that doctors work in has changed, the range of possible responses has grown further. But this growth has not been matched by a development of the processes and policies for considering and choosing the right response across all our functions.

We have used a range of responses instead of guidance in the past. These have included the development of supporting materials (such as GMP in action case studies, or the flowchart on raising concerns), sending letters from the Chair of Council or the Chief Executive, or promoting issues in GMC News, or through social media.

These can be very powerful responses but we are also able to influence the environments and systems that doctors work in, which in turn can have a significant impact on the values and behaviour that doctors exhibit. Examples of some of our regulatory levers include:

- deployment of the Response to Concerns Assessment Team
- tasking of the ELS team to address a particular issue
- lobbing employers/health authorities on system features that inhibit good practice (such as lack of protected time for CPD) - for example, through Employment Liaison Advisors (ELAs) or through letters from the Chief Executive or Chair of Council
- developing a more facilitative (intelligence led) role for the GMC as recommended by Shape of Training
- becoming more directive with medical royal colleges on addressing common fitness to practise issues within a particular specialty.

But, for the purpose of this review, the key question is not so much which regulatory levers we should exploit, but how well we understand what levers we have and how we make decisions to use them. Work to understand the range of regulatory responses available to

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18 ‘The GMC, in conjunction with other organisations, should develop mechanisms to help doctors and employers evaluate possible areas where CPD would benefit their patients or the service. This facilitative role should be evidence based.’ Shape of Training final report, para 124 (see reference at footnote 8).
the newly established patient safety intelligence forum should be an early task for its secretariat.

**Recommendation 12: We should use an intelligence led approach to thinking about the tools and levers available to us in seeking to protect patients, particularly when a rapid response is required.**

In the short term the new risk forum could helpfully consider the different approaches available. Over time it can help advise senior staff on the most appropriate response to a patient safety concern.

**We should work more systematically through trusted partners to target our guidance and extend our influence**

We know that doctors identify strongly with their medical specialty and turn to their medical royal colleges for specialty-specific learning materials. We also know that doctors are more likely to approach others (such as the medical defence organisations) for advice before they approach us. These organisations are already engaged in developing guidance and CPD materials that are targeted by specialty and by country, and they have a good understanding of the doctors they engage with.

The GMC is not best placed, nor resourced, to provide context-specific guidance to groups of doctors so we should seek to work more actively with bodies that have the right knowledge, relationships with doctors and governance to support the development of such products.

One option is that we develop formal partnerships and co-produce materials, such as CPD materials. But there are significant problems with this approach. It is likely to mean a significant investment of resource in terms of establishing contracts, and managing the process will limit the number of projects we can support. We may also need to navigate significant governance hurdles.

We should therefore focus greater efforts on influencing guidance and learning materials developed by others. For example, as our intelligence matures we should start to encourage the medical royal colleges and faculties - and if necessary apply pressure - to tackle issues that are prevalent in their specialties.

We should also consider how we can lend credibility to the work of others. The GMC has a unique selling point - we are the ultimate authority in terms of the professional standards of doctors. Our brand carries significant weight and the guidance of others will be given credibility if it carries our stamp. We already signpost doctors to guidance and resources created by others - such as the BMA, departments of health, and the medical royal colleges - both in our guidance and in responses to enquiries. We have also already identified - in the context of the development of the partnership policy - some of the key criteria for assessing potential partners.

We should consider how we can build on this to support the work of other organisations through use of our brand - for example, though some kind of trusted body status. This
approach carries risks – for example, we would not commit ourselves to line-by-line clearance of guidance or materials produced by others and we need to be very clear about what is and isn’t GMC guidance. But by establishing criteria for good practice in producing guidance based on GMP – perhaps going as far as a GMC hallmark – we can seek to influence and encourage the production of high-quality guidance and supporting materials that are more directly relevant to doctors’ day-to-day practice.

In taking this approach we are also able to focus our effort both on the production and on the dissemination of the core guidance and the development of a small number of high-quality products. We know that our case studies and scenarios are popular. They also provide us with a way of responding to problems in medical practice that are already covered by high-level guidance, but where examples of how the principles apply can support good practice.

**Recommendation 13: We should develop the concept of a trusted partner whose specific guidance and material we would not endorse but who we would recognise as a credible and trusted source of guidance to doctors on ethical issues.**

**We need to target our activities more effectively**

As we have become more outward facing and engaged we have sought to better understand our audiences and to be clearer on the purpose of our interactions with them. The GMC is currently developing audience profiles for each of our key audiences, and the output of this should be used to make progress on targeting our materials more effectively. The emerging agreement that we need a stronger intelligence function has a role here in contributing insights on how doctors engage with our guidance, including coordinating what we can learn from others about the place of behavioural science in informing our work.

But as it stands there is far more we can do with our own data and that of others to understand how doctors use our guidance and like to interact with it. In particular, we can do more to share information and insight between functions. We should have a view of the doctor population that is shared and that can inform all our work, from supporting the implementation of guidance to transacting with doctors in line with their preferences.

We also have an undeveloped understanding of where patients seek advice about what they can expect from their doctor. As part of this review we conducted an Ipsos MORI survey, which found that only a small proportion of the public seek advice on what to expect from their doctors (Annex G). Of those that have done this, most (21%) visited an NHS website. Of those that had not sought advice, an NHS website was first preference for 29% of respondents although it should also be noted that a combined total of 30% of respondents either stated ‘not sure’ or ‘none of these’. This supports our findings from *SOMEp* that patients find the system hard to navigate.

**Recommendation 14: We should draw on the skills and knowledge of those with marketing knowledge to target the delivery and presentation of our standards**
and guidance materials. In the short term we should use the outcomes of our audience profiling to make some progress on targeting our material.

**We need to address the gap in expectations that exists between what the public expect us to take action on and the action we take**

The difference between the standards we set and the threshold for taking action against a doctor’s registration creates what this review has described as an ‘expectation gap’ – that is, the perception that we raise expectations that the GMC will take action for failures that we will in fact never act upon (see section 3 above).

This is likely to lead to confusion and frustration for doctors and the public – over half of the complaints that are made to the GMC are closed at initial assessment, as they do not raise questions about a doctor’s fitness to practise. It also potentially undermines our credibility as a regulator. As more complaints are made to us and our work increases in prominence we should think carefully about how we want to respond to this issue.

This is a sensitive area and further work is needed to consider the pros and cons of the options available to us. These include:

- **Publishing and promoting guidance separate to GMP which sets out in some detail the circumstances in which we will take regulatory action.** A version of this already exists in the form of the indicative sanctions guidance, although this is directed at decision makers, rather than doctors or the public. A more explicit statement of the sorts of breaches of GMP that are likely to result in action against registration may provide clarity for decision makers and panels, and greater transparency for patients and doctors. It may also support consistency in a judgement-based process.

  It does however carry a risk of returning to the ‘blue book’ approach of minimum standards and of undermining the guidance as the standard expected of all doctors. This outcome would be incompatible with our overarching aim of helping to improve overall standards of professional practice (and not just to weed out bad doctors).

- **Broadening the statement on ‘serious or persistent failure to follow this guidance’ to state more accurately the circumstances in which the GMC is likely to take action – for example, when there is a risk to patients or public confidence might be undermined if the GMC did not take action.** This could give greater precision without losing flexibility in terms of how the guidance is used in decision making. It is however a highly detailed change, which is unlikely to have any great impact on public perceptions.
Considering using real cases from our fitness to practise procedures more prominently (for example, in e-bulletins to doctors) to show the kinds of cases in which the GMC takes action and to illustrate learning points. We already use anonymised fitness to practise cases to illustrate GMP principles on our website and have developed a process for anonymising cases to ensure that individual doctors are not upheld unfairly as examples (Annex H). The presentation of the cases on our website is relatively low key however, and the work to identify and present cases has not been seen as a high priority.

The GDC and defence unions use anonymised cases more prominently than we do (for example, in regular bulletins) and say that dentists/doctors like to engage with them.19 The postcard survey conducted as part of this review also found that doctors welcome real-life examples. We should therefore consider developing further this area of our work.

d Reviewing our communications– for example, to reconsider the language we use to describe those who raise concerns about doctors with the GMC.
Investigation officers in the Fitness to Practise Directorate have observed that by describing concerns that are raised about doctors as ‘complaints’ and by calling those who raise concerns ‘complainants’ we raise unrealistic expectations about the role of the GMC and the likelihood that the person raising the concern will receive redress.

Changing our language is only likely to go some of the way to managing public expectations however; we also need to work with others to help patients to direct their complaints to the right body.

**Recommendation 15: We need to recognise more openly the expectation gap between what we describe as good practice and what we take action on. A number of options are open to the GMC in helping to manage that gap.**

We need to confident that our decision makers are aware of the standards guidance and how it should be used in decision making

Decision makers in fitness to practise seem to vary in terms of their familiarity with the explanatory guidance and their understanding of what parts of the guidance may be relevant to the decision making process. For example, one case examiner queried with the review team whether ‘duties of a doctor’ is part of the guidance. Another commented that he did not have detailed knowledge of the explanatory guidance, but was confident that he could turn to a colleague who did.

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As set out in section 3, not all failures to meet the standards in *GMP* and the explanatory guidance will amount to an issue of impaired fitness to practise to a degree justifying action on the doctor’s registration. But we do need to be confident that our decision makers are aware of the standards guidance, and that our guidance for decision makers accurately reflects the specific aspects of the guidance on professional standards and ethics that would lead to action on a doctor’s registration.

An enhanced role for the Standards and Ethics Team in raising awareness of our standards guidance across the GMC will help to address this. We are also currently reviewing our guidance for fitness to practise panels, the *Indicative Sanctions Guidance*, and plan to consult on changes to that document in the autumn to ensure that it reflects the changes made to *GMP* and also that the threshold we apply for when to take action reflects what the public expects of doctors in 2014.

Our guidance for decision makers at the early stages of fitness to practise cases was updated last year when the new version of *GMP* was implemented. It would however be useful to revisit these and undertake a more fundamental review of the links with *GMP*.

**Recommendation 16: To undertake a review of the links with *GMP* in our guidance for decision makers in the earlier stages of our fitness to practise procedures.**

**The governance of our standards and ethics work**

Our governance arrangements changed significantly at the beginning of 2013, reflecting the Government’s policy aim of simplifying governance arrangements, and creating smaller and more ‘board-like’ structures.

The new model provides us with an opportunity to consider more consistently the evidence for revising or developing new guidance in line with the corporate strategy ambition to move towards a more risk-based model of regulation. The early work undertaken by the Intelligence and Insight Team to understand risk in medical practice demonstrates how our own data can inform decisions about the development of guidance and other materials.

But the delegation of the power to give guidance from Council to the Executive has also created some risks in terms of ensuring the continuing legitimacy and credibility of our guidance, as Council members are no longer involved in any significant way in the development of the content of the guidance. There is also some uncertainty about how we will make decisions to develop guidance or learning materials in the new model, and how decisions on content will be made.

We are still in a transitional phase as the new model beds in and this section considers the organisation-wide developments that are required to support the standards function and its operation as part of our wider work.
We need to be clearer about how we make decisions to develop or revise
guidance and learning materials

Until last year, all proposals for new guidance or learning materials were formulated by the
Standards and Ethics Team, overseen by the SEC and agreed by Council. The Standards
and Ethics Team also generated and analysed the evidence to support a proposal for new
guidance or materials and members of the SEC also contributed their own knowledge and
insights.

With the change of governance at the start of 2013 decisions about the revision of existing
guidance or learning materials, or the development of new guidance or learning materials,
are now made by the Strategy and Policy Board (SPB) with significant decisions on major
guidance being taken by Council.

We therefore need to describe the new model for making these decisions, which will
increasingly be informed by data and intelligence drawn from all areas of the organisation.
The Standards and Ethics Team has always sought to understand where there is a need for
guidance and will continue to be a significant contributor of intelligence. Together with
information from other internal and external sources we should be in a position to build a
stronger evidence base for the standards function work programme.

As it develops, the patient safety intelligence forum should help to weigh the evidence and
understand where we should take action. It should make recommendations for new or
revised guidance and learning materials for consideration and final decision by the chair the
SPB (which is subsequently reported to Council). It should also suggest where action other
than developing or amending guidance might be appropriate (see recommendation 12).

Finally, the SMT have an important role to play in ensure that there are sufficient resources
in place to support the work programme for guidance and that we are not over stretching
ourselves with additional work.

Recommendation 17: A governance model for guidance exists as described
above but we need to do more to make it understood.

We need more consistent management of cross-GMC projects to raise standards
of professional practice

Where projects require contribution from a number of teams across the GMC we need a
much more consistent approach to how we resource and support this work. This will be
ture of all new projects to develop guidance and learning materials (which will, as a
minimum, include staff from the Standards and Ethics Team and from the Strategy and
Communication teams).

To date such projects have mostly been managed through in-year negotiations between
assistant directors and other staff, which have been driven by the team responsible for the
project. This has led to misalignment of work plans, with resources to deliver critical
aspects of projects having to be negotiated when needed, rather than planned in advance.

We have a limited resource to support this work – whether it is within the Corporate
Communication Team, the Standards and Ethics Team or from colleagues in IS. We
therefore need to adopt a programme management approach to overseeing the high-level allocation of resources to deliver the promoting professionalism programme. This should include agreeing to project plans, committing resources, and monitoring progress against plans. The SMT need to ensure appropriate governance is in place to keep this work on track.

**Recommendation 18:** We need to have high level agreement on priorities and the allocation of resources on our work to promote professionalism, led by the SMT. In developing new materials or projects which seek to raise standards of professional practice we should use a programme management approach, supported by a staff member with experience of project management.

**In light of the changes to our governance structure we should develop new ways to get advice and help with developing guidance**

There is currently no standing group, either within the GMC, or acting in an external advisory capacity, whose role is to provide a space for reflection about GMC policy positions on ethical issues. In the past the SEC provided such a space. This has consequences both for the way in which we develop our guidance, and for our mechanisms for responding to difficult questions about how the guidance should be interpreted in a particular context.

*During guidance development*

We have not developed any new standards and ethics guidance since the change in governance arrangements, and the Standards and Ethics Team has expressed concern that uncertainty remains about how some of the functions previously carried out by the SEC will be delivered.

For example, during the guidance development process, policy and operational questions will inevitably arise that are not controversial (and so do not need a board-level policy decision) but do need a view to be taken. Recent examples include questions about:

- the boundaries between different pieces of guidance (specifically, whether a question about information sharing should be explored in the consultation on prescribing or the consultation on *GMP*)
- the phrasing of a particularly sensitive piece of guidance (specifically, how we wish to express what help a doctor can give to a patient requesting advice on suicide)
- the remit of a piece of guidance (specifically, whether the child protection guidance should cover all children at risk of harm, or whether it should be restricted to those at risk of serious harm).

The SEC provided a forum for decision making on issues of this nature, and was also able to challenge policy positions recommended by working groups, which were independent and ultimately not accountable for the final content of GMC guidance.

It may be that over time the SPB will have scope for this level of policy discussion but so far it has not had the space, expertise or resources to do so. In the current model, these policy and operational decisions will therefore be taken by senior staff, advised by the Standards and Ethics Team.
We also receive complex enquiries on the application or interpretation of the guidance that need a specific GMC policy decision or present reputational risks for the GMC. A recent example was an enquiry from NHS England about the ethics of publishing details about a healthcare worker whose medical condition may have posed a risk to patients.

The current position delegates a significant amount of responsibility to staff for decisions on GMC guidance and this presents a risk. Without a clear publicly understood process for considering and reaching decisions on issues related to ethical practice or interpretation of the guidance there could be a risk, not least in terms of defending legal challenges. The SEC’s minutes were available and disclosable under the Freedom of Information Act or to a court considering whether the guidance is lawful.

Other approaches within the new governance model

One option would be to create an external advisory group on standards and ethics, along the lines of the existing Education and Training Advisory Board. Doing this would allow us to recruit experts from a wide range of backgrounds to inform our policy decisions on contentious issues. This would give us access to a similar skills set to that provided by SEC, although it would not have the accountability that the SEC had.

Another approach would be to create a small internal forum whose role would be to oversee the policy development of guidance, and support the Standards and Ethics Team and Director of Education and Standards in forming policy positions in response to complex enquiries. It could, for example, be made up of the Assistant Director (AD) for standards, other members of the Standards and Ethics Team as appropriate, the Senior Medical Adviser and/or another doctor, and a small number of other ADs whose responsibilities have a significant relationship with standards (such as fitness to practise, the in-house legal team, and the media team).

While such a forum would not have the breadth of knowledge of the SEC, or be representative of external interests, it would have some accountability and would build our resilience and knowledge base at a senior level for agreeing GMC policy positions. This would help to manage some of the risks around transparency that the current arrangements pose.

Recommendation 19: We should clarify how staff with responsibility for our standards and ethics work will be supported to make policy and operational decisions on standards and ethics. The options are:
a. the Standards and Ethics Team will advise, as at present

b. we create an internal standards and ethics advisory group

c. we create an external standards and ethics advisory group

We should develop criteria for when we initiate a task and finish group and a process for how members are selected

In the past we have brought together specialists and representative of different interests in time-limited groups to provide knowledge or expertise around a specific piece of work. One of the key benefits of time-limited groups is that they provide a space for informed debate of issues that are often contentious and on which we can expect some external challenge. Through these groups we also establish relationships with key influencers who can champion our guidance in the medical community and beyond.

Under the new governance structure it is clear that the SPB has the responsibility for agreeing time-limited groups, but there are no express criteria for when one should be established, or a process for identifying members for standards work. The Standards and Ethics Team should therefore decide how it would wish to use the groups, how and when it would seek to develop them, and its approach to agreeing the members.

**Recommendation 20: We should continue to use task and finish groups for the development of guidance. The Standards and Ethics Team should lead on the identification of candidates, with advice from other directorates, for approval by the SPB.**

Consultation on new guidance must be proportionate to the issues

During this review we encountered some frustration with the amount of time it takes to develop new guidance. This is understandable, given the high-profile nature of our work and the media interest in what we do, but in reality the length of time to develop guidance varies greatly. A substantial piece of guidance can take two years to develop, with a standard consultation period of three months. Shorter and simpler pieces of guidance take much less time. For example, the ten pieces of explanatory guidance published in 2013 were developed within a year, with a consultation period of six weeks.

The legitimacy and credibility of GMC guidance are reliant on appropriate engagement and consultation and we have made mistakes in the past. For example, when developing a new edition of *Confidentiality* in 1998 we identified the correct legal position in terms of the legal basis for using identifiable patient information for research purposes, but this did not accord with NHS practice. In effect we created new duties for the NHS that it wasn’t set up to meet. As a result we received considerable criticism in medical journals and elsewhere from major players such as the Department of Health, the cancer registries, and the World Health Organisation. This caused reputational damage that took a long time to repair. The fact that we were right was no compensation for our failure to take others with us.
Proportionate consultation is also key to defending legal challenges. A defence to judicial review is that the guidance development process is open and fair, and that the decision making process is well informed, rational and transparent. As a public body making statements that directly affect the treatment and care of patients all of the advice we give is open to legal challenge. We have had one major judicial review of our guidance (the Burke case in 2004-2005\textsuperscript{20}); a threatened judicial review that led to the development of the guidance for decision makers on assisted suicide (the AM case in 2011-12\textsuperscript{21}); and a number of cases in which our guidance is cited (including the recent approving comments in the Supreme Court)\textsuperscript{22}.

The quality of our consultation and engagement will also be particularly important following the changes in our governance arrangements at the beginning of 2013. Previously, the development of the content of guidance was overseen by a committee that represented external communities of interest, both lay and medical. Decisions on content of guidance in the new model will be made by employees of the GMC, rather than members of Council. We must therefore ensure that we are able to validate our decisions through reference to evidence obtained through consultation and engagement.

Consultation must however be proportionate to the issues. A review of GMC consultation processes is planned and should consider further how this principle applies in all of our consultation practice.

**Recommendation 21:** Ensuring consultation is proportionate to the issues is an important principle to maintain. The review of GMC consultation processes should take into account the findings of this review when developing a new GMC consultation protocol.

**We need to prepare for a future in which shared statements by regulators on core principles become more common**

There is a growing emphasis in the health and social care environment on joint working between health and social care professionals and their regulators. The ambition is to reduce duplication and information overload for healthcare professionals, and to encourage consistency in standards of professional conduct within multidisciplinary environments. This was a key theme in the Law Commission consultation on the future of healthcare regulation\textsuperscript{23}, the Keogh review of cosmetic procedures\textsuperscript{24}, as well as in the Francis report\textsuperscript{25}.


\textsuperscript{22} See footnote 4 above for the reference.

\textsuperscript{23} See footnote 16 above.
In the recent information governance review, Dame Fiona Caldicott recommended ‘that the health and social care professional regulators must agree upon and publish the conditions under which implied consent can be relied upon’. The Professional Standards Authority (PSA) has been commissioned by the Department of Health to oversee this work, to conclude by September 2014.

The proposed work on implied consent creates some immediate questions for the GMC (and other professional regulators such as the Nursing and Midwifery Council (NMC) and GDC, with whom we have had informal conversations during this review):

- What model of joint statement do we prefer? Previous joint statements (such as the NMC/GMC joint statement on professional values) do not appear to have had a large reach and there are questions about how shared statements might be seen as credible by doctors, how detailed they need to be in order to be beneficial for patients, whether they would add an extra layer of complexity and how they might be used in our fitness to practise processes.

- Would we be content to stop giving guidance on matters that are covered by joint statements and how does this fit with our regulatory responsibility to give guidance on matters that we might take regulatory action over?

- What is the governance model for agreeing our position on key policy and content questions?

In the short term we could establish a task and finish group – either of external experts as part of the planned review of Confidentiality or of senior officials within the GMC – to consider these questions and oversee our immediate engagement with the PSA commission on implied consent.

In the longer term, we need to consider how we will manage the greater number of requests for joint statements in the context of the Law Commission work.

**Recommendation 22: In the short term we should establish a task and finish group to oversee our immediate engagement with the PSA commission. In the longer term, we should consider the governance of joint statements in the context of the Law Commission work.**

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Review of governance agreed as part of internal audit work for 2014 should consider the impact of the changes on our standards work

The change in our governance arrangements - in particular the delegation of power to give guidance from Council to the Executive - is a very significant change in how we go about agreeing guidance. Council is now responsible for overseeing the process of agreeing standards of good practice, but is not involved in any significant way in the development of the content. This is likely to be a long-term feature of our work.

As with the rest of the governance structure it is still relatively early days. We have not yet developed new guidance under this model and the executive boards have yet to engage on a difficult ethical dilemma. Recommendations in this report, if adopted, will provide a new framework to support decision making around our standards work.

But the review of the implementation of the governance model provides an opportunity to take stock and consider the changed relationship between Council and the Executive on our standards work from a governance perspective.

Recommendation 23: The review of governance agreed as part of internal audit work for 2014 should consider the impact of the changes on our standards work including the operation of the delegation of power from Council to the Executive.
Standards review: breakdown of recommendations

Operational delivery

**Recommendation 1:** There is no case at present for changing our core approach to giving guidance on professional standards and ethics.

**Recommendation 2:** All of the guidance should remain applicable to all doctors to the extent that it applies to their work.

**Recommendation 4:** In all new or revised explanatory guidance its relationship with the high-level principles in the core guidance should be explicit.

**Recommendation 5:** We need cross-organisational agreement that the focus of the Standards and Ethics Team’s work should be:

- the development and revision of guidance
- the development of the content of learning materials (but not the development of the overall product, which should sit with the Strategy and Communication Directorate)
- provision of complex advice
- support of internal training on standards and ethics issues (see recommendation 7 below)
- external engagement on issues where expert knowledge of the guidance is needed.

**Recommendation 6:** Responsibility for implementation of guidance should not rest with the Standards and Ethics Team. The team should advise on content to ensure that the integrity of our guidance is maintained.

In the short term the Standards and Ethics Team and the S&C teams that have a role in implementing the guidance (RLS, DO’s, Corporate Communications and Relationships and Campaigns) should review their immediate work plans to identify existing commitments that might require support from the Standards and Ethics Team and agree the support that the Standards and Ethics Team can provide.
Recommendation 8: We should continue to provide advice on our standards and ethics guidance but the delivery model should be reviewed. The team working on the ethical enquiries business improvement project should consider what it can draw from this report to support its work. In particular the team should consider the costs and benefits of providing the advice service.

Recommendation 9: When the organisational structure of the GMC is next considered, perhaps linked to the appointment of a new Chief Operating Officer, consideration should be given to the Standards and Ethics Team becoming part of a central function that has the experience of managing relationships across the organisation.

Recommendation 18: We need to have high level agreement on priorities and the allocation of resources on our work to promote professionalism, led by the SMT. In developing new materials or projects which seek to raise standards of professional practice we should use a programme management approach, supported by a staff member with experience of project management.

Recommendation 20: We should continue to use task and finish groups for the development of guidance. The Standards and Ethics Team should lead on the identification of candidates, with advice from other directorates, for approval by the SPB.

Recommendation 21: Ensuring consultation is proportionate to the issues is an important principle to maintain. The review of GMC consultation processes should take into account the findings of this review when developing a new GMC consultation protocol.

Dissemination of guidance

Recommendation 3: We need a fundamental overhaul of how we organise and present the guidance. In the short term:

- The A to Z index should be restored as a priority.
- The structure of the explanatory guidance page should be reviewed to find ways of helping the reader to find what they are looking for.

Recommendation 13: We should develop the concept of a trusted partner whose specific guidance and material we would not endorse but who we would recognise as a credible and trusted source of guidance to doctors on ethical issues.

Recommendation 14: We should draw on the skills and knowledge of those with marketing knowledge to target the delivery and presentation of our standards and guidance materials. In the short term we should use the outcomes of our audience profiling to make some progress on targeting our material.
**Recommendation 15:** We need to recognise more openly the expectation gap between what we describe as good practice and what we take action on. A number of options are open to the GMC in helping to manage that gap.

**Embedding our standards work internally**

**Recommendation 7:** The role of the Standards and Ethics Team should be extended to include the development of a new internal training resource. This could be through partnering with an external training company, or employing staff with experience of developing and delivering relevant training programmes, or another model.

In the short term we need to recognise that the resource available to the Standards and Ethics Team to provide training to others is very limited. The creation of such capacity should be prioritised.

**Recommendation 10:** We should consider how we can develop the culture of sharing policy ideas across the GMC, coordinated by the Strategy and Communication Directorate.

**Recommendation 16:** To undertake a review of the links with GMP in our guidance for decision makers in the earlier stages of our fitness to practise procedures.

**Making decisions on our guidance**

**Recommendation 11:** We need to be much more intelligence led in making decision that about our guidance.

In the short term we should develop criteria for when guidance is, and isn't, the right response, which should be agreed by the Strategy and Policy Board. A schedule for reviewing existing guidance, and criteria for reviewing guidance outside of the normal schedule, should also be developed and agreed with the Strategy and Policy Board.

**Recommendation 12:** We should use an intelligence led approach to thinking about the tools and levers available to us in seeking to protect patients, particularly when a rapid response is required.

In the short term the new risk forum could helpfully consider the different approaches available. Over time it can help advise senior staff on the most appropriate response to a patient safety concern.

**Recommendation 17:** A governance model for guidance exists as described above but we need to do more to make it understood.
**Recommendation 19:** We should clarify how staff with responsibility for our standards and ethics work will be supported to make policy and operational decisions on standards and ethics. The options are:

- the Standards and Ethics Team will advise, as at present
- we create an internal standards and ethics advisory group
- we create an external standards and ethics advisory group

**Recommendation 22:** In the short term we should establish a task and finish group to oversee our immediate engagement with the PSA commission. In the longer term, we should consider the governance of joint statements in the context of the Law Commission work.

**Recommendation 23:** The review of governance agreed as part of internal audit work for 2014 should consider the impact of the changes on our standards work including the operation of the delegation of power from Council to the Executive.
3 - Standards work programme for 2014 and oversight of guidance

Standards work programme
### Research Forum Approval

1. Agree scope for drafting
2. DH review meeting
3. Publish Response documents

**Topics agreed for consultation**
- Draft implied consent/agree confidentiality scope
- Scope agreed for engagement
- Joint statement published
- Draft implied consent/agree confidentiality scope
- Scope agreed for engagement
- Joint statement published
- Draft implied consent/agree confidentiality scope
- Scope agreed for engagement
- Joint statement published

**S&C leading to develop joint statement, with Standards input**
- Joint statement on candour
- GMPiA and online content
- FtP online cases
- Research – overseen by Standards and Intelligence Unit

**Externally driven projects**
- Input to developing draft guidance
- Promoting the guidance
- Scoping and drafting explanatory guidance?

**Internally driven projects**
- Leadership Alliance development of system-wide response
- Standards and S&C teams plan, design and deliver website content, promotional events and partnership programmes

**Business as usual**
- Business as usual responsibility subject to ethics review recommendations – resource implication unknown
- Unpredictable demand – as issues arise (~4 major inquiries per month)

### Schedule

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<th>Week</th>
<th>March</th>
<th>April</th>
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**Resource intensity illustrated by strength of shading**
- Resource intensity illustrated by strength of shading

**Oversight Group**
- Agree consultation draft
- Consultation on draft EG
- Consultation?

**Ethical correspondence: 40-50 per month**

**Business as usual**
- Conferences, BMA ethics committee, speaking engagements
- Approximately one per month – 3 days staff time
### Drivers and risks of current standards projects

<table>
<thead>
<tr>
<th>Project</th>
<th>Key drivers</th>
<th>Key milestones/delivery date</th>
<th>Risks</th>
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<tbody>
<tr>
<td>PSA-led work on implied consent for sharing confidential information</td>
<td>The Information Governance Review (Caldicott2) recommended that the professional regulators should agree conditions for relying on implied consent.</td>
<td>The current aim is to publish the conditions in September 2014.</td>
<td>The project has not yet started. The key risk is slippage in the timetable for delivery, with implications for our autumn work programme.</td>
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<tr>
<td>Review of our confidentiality guidance</td>
<td>This is a scheduled review. It will also be the vehicle for incorporating the outcomes of the PSA work into our guidance.</td>
<td>Begin formal engagement autumn 2014, and consultation in early 2015.</td>
<td>Key risk is that the timetable is dependent on the delivery of the PSA work.</td>
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<td>Review of Standard and Ethics Team’s correspondence process</td>
<td>Customer service improvement project – the steady growth in complexity of enquiries has made it essential to identify improvements to reduce cost and time and</td>
<td>Final recommendations by end of April/early May 2014.</td>
<td>Key risk is ability to resource the delivery of the review and implement findings.</td>
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<tr>
<td>Project</td>
<td>Key drivers</td>
<td>Key milestones/ delivery date</td>
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<td>Private and cosmetic practice</td>
<td>This project is responding to issues highlighted in the Keogh Review of cosmetic interventions, and the Competition and Markets Authority report into private healthcare. Private practice accounts for a higher-than-average rate of fitness to practice cases and raises ethical concerns that are not addressed by our existing guidance.</td>
<td>Initial consultation Sept-Oct 2014&lt;br&gt;Formal consultation March-June 2015&lt;br&gt;Implementation Dec 2015 – April 2016.</td>
<td>Key risk is changes to the timetable for delivery. This has been agreed with DH but there could be pressure to deliver sooner. We will need to define the scope of the guidance carefully to avoid unintended consequences for the NHS sector.</td>
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<tr>
<td>Duty of candour</td>
<td>The Government’s response to the Francis Report makes a number of commitments in respect of candour, including that the GMC and NMC should work with the other health and social care regulators to agree</td>
<td>Joint regulatory statement on duty of candour by the end of June 2014.</td>
<td>Key risks include failure to achieve consensus on joint statement; work programmes of the other regulators preventing timely delivery; public engagement introducing unforeseen</td>
</tr>
<tr>
<td>Project</td>
<td>Key drivers</td>
<td>Key milestones/ delivery date</td>
<td>Risks</td>
</tr>
<tr>
<td>---------</td>
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<tr>
<td></td>
<td>consistent approaches to candour and reporting errors.</td>
<td>Consulting on new explanatory guidance before the end of the year.</td>
<td>issues (eg lack of understanding about candour); ability to resource the engagement part of the process.</td>
</tr>
<tr>
<td>Senior named accountable clinician</td>
<td>In response to the Francis Report the Academy of Medical Royal Colleges was commissioned to develop guidance on senior accountable clinicians. The Independent Review of the Liverpool Care Pathway raised similar issues. We need to consider whether additional GMC guidance is needed.</td>
<td>Academy will publish May/June 2014</td>
<td>Political risks in terms of four country coverage of our guidance. The Academy guidance applies to England only. At this stage not clear whether the other jurisdictions will establish a similar role.</td>
</tr>
</tbody>
</table>
3 - Standards work programme for 2014 and oversight of guidance

Draft terms of reference for Task and Finish Groups for guidance development projects

Purpose

Section 35 of the Medical Act 1983 (as amended) provides the General Medical Council with the power to ‘provide, in such a manner as the Council thinks fit, advice for members of the medical profession on standards of professional conduct; standards of professional performance; or medical ethics’.

The GMC provides this advice in the form of guidance on good practice, which sets out the standards of competence, care and conduct that the GMC expects of all doctors.

The GMC’s Strategy and Policy Board has agreed that work should start to develop new/revised guidance on [Private and Cosmetic Practice/ Confidentiality]. It has agreed to set up a Task and Finish Group, comprised of members external to the GMC, to help inform this work.

Role of the Task and Finish Group

The role of the Task and Finish Group is to advise on the content and structure of guidance. It will gather and consider evidence to inform the development of draft guidance; make policy recommendations; and submit a consultation draft to the Strategy and Policy Board for approval.2

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1 This is a generic framework that will be adapted if required to reflect the specific guidance topic which a particular group is convened to develop. Task and Finish Groups will only be established for major guidance development projects (i.e. Good medical practice and explanatory guidance that addresses core themes such as consent, confidentiality and end of life care).

2 Under the new governance arrangements not all guidance on standards and ethics will be submitted to Council for approval. This decision will be taken on a case by case basis, taking into account the
The GMC’s remit is UK wide and the Group’s approach to developing guidance must take account of that fact. Bearing in mind the GMC’s role and remit, the Group will need to consider:

a what should be the core issues for inclusion in [updated] guidance

b whether and how any related issues should be addressed by the GMC

Membership

The Task and Finish Group should have a membership that reflects a variety of professional, public and employer perspectives from across the UK. The group should be able to provide input on the ethical and legal considerations, healthcare policies and practice, and the views and experience of professionals, patients and other key interest groups. The Chair will be nominated by the Director of Education and Standards and approved by the Chief Executive of the GMC.3

The Task and Finish Group will be comprised of:4

■ At least one licensed medical practitioner with clinical experience that is relevant to the guidance under development
■ At least one member of a professional organisation that represents the interests of doctors
■ At least one member of an organisation that represents the interests of patients
■ At least one member from an employer or service provider organisation
■ At least one member of a medical education and training organisation
■ At least one member from each of the four countries of the United Kingdom
■ At least one member who can provide legal and ethical advice that is relevant to the guidance under development

strategic significance of the guidance and the extent to which it establishes new principles of good medical practice. Guidance on core themes is likely to require Council approval.

3 The decision on whether the Chair will be an internal or external appointment will be taken on a case by case basis, taking into account the strategic importance and potential sensitivity of the issues under discussion. An external Chair is likely to be appointed in cases where it would be helpful to emphasise that the GMC is approaching the review with an open mind. In all cases the Chair should be someone of standing who can command respect from both the public and profession.

4 We will appoint people with specific expertise in the area of guidance under development and other individuals reflective of key interest groups including patients and the public. Candidates will be identified by the Standards and Ethics Team during the scoping phase of projects, with the help of staff in our Wales, Scotland and Northern Ireland offices. In cases where suitable candidates cannot be identified in this way, organisations with an interest in the guidance will be asked to nominate individuals.
At least one member from an organisation representing a nursing (or other health or care professional) perspective

Group members will participate as individuals, applying their particular experience and knowledge to the issues under consideration, rather than representing the interests of any particular organisation.

**Duties**

- **a** To review the content of any existing GMC guidance relevant to the issues under consideration
- **b** To consider evidence presented by the secretariat about current policies and practice and the nature of existing or emerging concerns about good practice relating to [guidance subject]
- **c** To consider the implications of developments in the law and any current ethical debates which bear on [guidance subject]
- **d** To identify and consider any work other organisations have done, or are doing, on issues in [guidance subject] and how this might relate to or complement any GMC guidance
- **e** To advise on the scope and structure of new guidance; recommend the policy positions to be adopted; and support development of the draft text, taking account of the need for consistency with the principles underpinning other GMC guidance
- **f** To consider ways in which key interest groups can contribute to the development of the draft guidance from the initial drafting into the public consultation stages
- **g** To oversee any external engagement and evidence gathering activities that support drafting of the new guidance
- **h** To agree a consultation draft of new guidance for submission to the GMC Strategy and Policy Board
- **i** To review the results of formal consultation exercises and to make recommendations about revisions to the guidance based on the analysis provided
- **j** To consider ways in which the new guidance should be promoted and its impact assessed
- **k** The Task and Finish Group will be dissolved when the guidance is published
**Timetable**

The aim is to produce draft guidance for consultation by [Insert date] with a view to publication in [Insert date]. An outline project plan will be provided by the secretariat and any subsequent changes to milestones and meeting dates will be negotiated through the Chair.

The Group will meet approximately five times for approximately 2 hours each time. Work will also be progressed by e-mail where possible.

**Reporting**

The Group will provide regular progress reports to the Director of Education and Standards, who will report to the Strategy and Policy Board.

**Secretariat and attendance**

The GMC Standards and Ethics Section will provide secretariat support to the Group. This will include background research, drafting papers and guidance, planning and delivery of engagement and consultation activities, analysing and providing reports on the outcome of public consultation. The secretariat will record actions and minutes for each meeting.

Agendas and draft papers will be agreed between the Assistant Director for Standards and Guidance and the Chair of the Group.

The Director of Education and Standards and other GMC staff with relevant policy or operational responsibilities will attend as required for the discussion of agenda items.

**Confidentiality and Freedom of Information**

Reports on the development of the project will be made public throughout the process.

Agendas and agreed minutes will not be published, although they can be disclosed in response to a request under the Freedom of Information Act 2000. Task and Finish Group papers and discussions at meetings are expected to be treated ‘in confidence’ and not disclosed to third parties without prior agreement. Members will be expected to direct any enquiries from journalists to the GMC media team.

Members should be aware that the GMC is a public body and that information it holds is subject to the Freedom of Information Act 2000 (including papers, e-mails and other correspondence). This means that e-mails, papers and other documents related to the work of the Group (from which members may be identifiable) may be released where there is a relevant request.

**Fees and Expenses**

Members of the Group will not be remunerated unless they are existing GMC Associates. Travel and subsistence expenses will be paid in line with the GMC’s policy.
for Council members and Associates. If an external Chair is appointed, remuneration will be determined by the Chief Executive.
### Existing learning materials - estimated resources and costs required to update and maintain

<table>
<thead>
<tr>
<th>Learning resource</th>
<th>Visits in last 12 months(^1)</th>
<th>Main activities</th>
<th>Estimated FTE/quarter</th>
<th>Additional costs</th>
</tr>
</thead>
</table>
| **GMP in Action:** developing new scenarios and updating/maintaining current content | 32,800 | • Develop and test high level options for content  
• Draft content  
• Testing content – clinical realism, four country relevance  
• Production, design, upload  
• User testing  
• Promotion  
• Update and maintain | Standards L3 (21 days)  
S&C L3 (5 days)  
Standards or S&C L4 (5 days)  
IS and/or webteam (1 day) (to develop 4 new scenarios each quarter) | Purchasing images and/or arranging photoshoots |

\(^1\) Data on visits from 1 April 2013 to 31 March 2014
<table>
<thead>
<tr>
<th>Learning resource</th>
<th>Visits in last 12 months</th>
<th>Main activities</th>
<th>Estimated FTE/ quarter</th>
<th>Additional costs</th>
</tr>
</thead>
</table>
| **Learning disabilities website:** developing/ commissioning new material; updating and maintaining current content | 20,900 | • Scoping and research  
• Writing and structuring content  
• Testing  
• Production, design, upload  
• Promotion  
• Update and maintain | Standards L3 (8 days)  
S&C L3 (5 days)  
S&C or Standards L4 (5 days)  
Standards L4 (10 days)  
(adding new content twice a year) | Potential for costs if decide to commission additional content from external agencies |
| **Fitness to practise cases**  
– anonymised and summarised determinations linked to principles in the guidance | 3,272 | • Selection of cases; assigning to relevant GMP paragraph  
• Anonymising and summarising  
• Uploading new and removing old cases | FtP L4 (7 days)  
Standards L4 (6 days)  
S&C L3 (4 days)  
(on-going updates every quarter) | |
| **All other learning materials** (podcasts, case studies, presentations, raising concerns flowchart)  
Updates and maintenance | 51,526 | • Checking terminology  
• Checking external links  
• Amends/updates to accommodate new guidance/policies | S&C or Standards L4 (5 days)  
IS and/or web team (2 days) | Possible external expertise required in some cases |