General Medical Council response to proposed legislation to encourage medical innovation

April 2014

Introduction

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

   - We set the standards that are required of doctors practising here.
   - We decide which doctors are qualified to work in the UK and we oversee their education and training.
   - We make sure that they continue to meet these standards throughout their careers.
   - We take action when we believe a doctor may be putting the safety of patients at risk.

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

3. This memorandum sets out the GMC’s views on the proposed legislation to encourage medical innovation.

GMC overall position

4. Medicine is a risky business. There are many people alive today due to the willingness of doctors to innovate, deal with uncertainty and take reasonable risks which are understood by, shared with, and consented to by, the patient.

5. It is fundamentally important that doctors continue to feel able to innovate when it is appropriate to do so. We are therefore wholly sympathetic with the aims of the Bill.

6. We are however concerned that legislation which aims to clarify and encourage good practice in terms of when medical innovation is responsible could have the opposite effect as well as unintentionally weaken the principles which we regard as fundamental to safe, effective patient care. We take the view, therefore, that legislation is both unnecessary and undesirable.
Context of the GMC and the medical innovation

7. **Good Medical Practice**, our core guidance for all doctors, states that doctors must ‘be satisfied that the drugs or treatment serve the patient’s needs’ and must ‘provide effective treatments based on the best available evidence’.  

8. Innovative treatments are subject to the same principles of good clinical decision-making and patient consent as all forms of treatment. Of course where innovative treatment is concerned the evidence of effectiveness in relation to a particular condition or patient profile may be very limited or lacking. This would not prevent the use of the treatment but would have implications for how doctors sought consent from the patient or, in the case of a patient who lacked capacity to decide, how doctors involved the patient’s healthcare legal representative or family in the decision.

9. Our guidance on **Consent** already recognises and allows for innovation. It states that doctors must give patients the information they want or need about ‘whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.’ The patient (or those close to the patient) should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties.

10. Since evidence of the effectiveness of innovative treatments will likely be limited compared to established treatments, it’s all the more important that the doctor shares information with the patient in an honest and open way about what is known and not known, about the benefits and risks of the innovative treatment, and why it is being proposed, but our guidance certainly does not discourage innovation.

11. Doctors who make decisions based on the principles in our guidance will be able to justify their decisions and actions if we receive a complaint about their practice. In cases where our guidance has been followed, this may well also reduce the likelihood of litigation in the Civil Courts.

GMC general comments on the Bill

12. A separate legal framework specifically for decisions about innovative treatment which provides freedom for doctors to step outside the norms of practice would also need to put in place sufficient safeguards against dangerous practice or exploitation of patients’ lack of medical knowledge.

13. While the Bill attempts to do this, it is unclear in a number of key areas. For example its definition of ‘responsible innovation’ is multi-layered and complex; the duties it places on doctors in terms of ‘taking account of opinions expressed by colleagues’ are not spelled out; neither does it define or describe an ‘accountable process’ except to a limited extent in the explanatory notes. We also note that it

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1 GMP p7 [http://www.gmc-uk.org/static/documents/content/GMP_2013.pdf_51447599.pdf](http://www.gmc-uk.org/static/documents/content/GMP_2013.pdf_51447599.pdf)

2 Consent p10 [http://www.gmc-uk.org/static/documents/content/GMC_Consent_0513_Revised.pdf](http://www.gmc-uk.org/static/documents/content/GMC_Consent_0513_Revised.pdf)
does not attempt to define the concept of ‘accepted medical treatments’ which would seem important as a yardstick to help doctors decide whether their proposed treatment satisfies the other provisions of the Bill. Any lack of clarity in legislation of this kind can only serve to undermine any safeguards aimed at deterring dangerous practice or reducing the risk of exploitation.

14. We are also concerned that these areas of uncertainty within the Bill could hinder responsible innovation, in particular where it is not clear what actions by particular doctors are being mandated by specific provisions. For example, one of the proposed safeguards for innovative treatment is notification of the doctor’s responsible officer (RO). ROs are typically responsible for a large number of doctors who are spread across a wide range of specialties, settings and geographical areas. In cases where doctors need to make an immediate or urgent decision with the aim of saving a patient’s life, stopping to notify and get acknowledgement from the RO could delay them from taking some of the responsible risks they are able to make under current arrangements. If it’s envisaged that ROs will do more than just take receipt of notifications, it’s important to note that ROs may not be in a position to advise or comment on proposed innovative treatment for a particular patient given that the RO may not know anything about the patient or have any specialist knowledge in the field. If the expectation is that ROs would have to advise doctors or offer some form of ‘assurance’ around the doctor’s decision, this would involve substantially changing the role and remit of ROs. This would have resource and other implications for NHS and independent sector services, add unwelcome layers of bureaucracy, and require changes to the Medical Act which would be virtually impossible to draft in a meaningful way.

GMC responses to specific consultation questions

15. Please find below some comments upon some of the questions in the consultation where we have specific feedback.

*Question 3 - Do you agree with the circumstances in which the Bill applies, as outlined in clause 1(3)? If not, please identify any changes you suggest, and give your reasons for them.*

16. Clause 1(3) seems to suggest that innovation is only present when a body of responsible colleagues may or do disagree with the opinion of the doctor who is proposing to perform a treatment that departs from accepted practice. We do not understand this to be the desired definition given the stated aims of the Bill. A proposed innovative treatment for a patient may be supported by one group of doctors, even if a different group of doctors would challenge its use.

*Question 4 - Do you have any comments on the matters listed in clause 1(4)-(5) on which the doctor’s decision must be based for it to be responsible? Are there any that should be removed, or changed, or added, and if so why? For example, should the Bill explicitly indicate that the other treatments mentioned in 1(5) (a)-(c) include treatments offered as part of research studies?*
17. Clauses 1(4)-1(5) appear to be an attempt to describe current good practice in seeking consent from a patient, or in discussing the options that may be in the best interests of a patient who lacks capacity to decide.

18. As a legal framework, we believe that clauses 1(5)a - 1(5)d are a less clear description of good practice than those already set out in the Mental Capacity Act 2005 (and its supporting code), and in the case law relating to obtaining consent from patients who have capacity to make their own decisions. We have reflected this existing legal framework in the GMC's Consent guidance. Adding a slightly different description in this Bill would require that much clearer lines are drawn between this and existing legal obligations, failing which the Bill would introduce new areas of uncertainty for doctors and others.

19. Furthermore, we believe that clause 1(5)e is an unhelpful addition to the current practice. It suggests that doctors should take account of the opinions of 'those doctors who they wish to', and places on them no obligation to take account of the opinions of doctors who have relevant clinical expertise in the area. As currently drafted, this addition removes an important safeguard for patients by removing a key requirement of responsible practice.

Question 5 - Do you have any comments on the process set out in clause 1(6)-(7)? Are there any provisions that should be removed, changed or added – and if so, why?

20. We would support clause 1(6) as an attempt to define, at a high level, what constitutes a responsible decision. However, we note that this clause would conflict with clause 1(5)e which suggests that doctors should take account of the opinions of those doctors who they wish to, rather than the opinions of doctors who have relevant clinical expertise.

21. The formulation of clause 1(7)a lacks clarity on the expectations in relation to gaining informed patient consent. It is unclear whether the intention is that doctors should provide information that a “reasonable patient” would expect to receive, as is the case in current case law (following the Bolitho case and Chester v Afshar (2004)).

22. It is unclear how clause 1(7)b is suggesting doctors’ decisions should be made with multi-disciplinary teams. The role of the multi-disciplinary team is not defined and it is unclear as to whether it would have an advisory role or an authoritative role in clinical decisions. As drafted, it is difficult to see how this would be interpreted in law, which would introduce further uncertainty for doctors and members of any multi-disciplinary team.

23. As stated previously, we also have concerns about the proposals with regard to ROs as detailed in clause 1(7)c.

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3 Consent p10 http://www.gmc-uk.org/static/documents/content/GMC_Consent_0513_Revised.pdf
Question 8 - Do you have any comments and suggestions for inclusion in the draft impact assessment and equality analysis?

24. The consultation document asks for comments upon what impact the legislation might have upon research. As currently drafted we believe that the Bill does not provide a clear enough definition of medical innovation so as to define where the boundary lies between innovation and medical research. Our understanding is that this bill is aimed at doctors innovating to meet the needs of a particular patient. Whereas our understanding would be that innovation for a whole population of patients constitutes medical research, for which legislation and GMC guidance⁴ already exists.

Conclusion

25. We are committed to playing our part in helping patients to benefit from world leading medical treatment delivered by doctors who feel free to innovate, deal with uncertainty and take reasonable risks which are understood by and shared with the patient. In doing so we hope that medical advances can continue to be made in line with the ambitions outlined in the consultation report.

26. However, while we are wholly sympathetic with the aims of the Bill, we do not consider that further developments in medical innovation can be best achieved by legislation drafted in these terms. Although the Bill aims to clarify and encourage good practice in responsible medical innovation we believe that it could have the opposite effect as well as unintentionally weakening the existing principles which we regard as fundamental to safe, effective patient care.

27. We believe that much more can be done to promote responsible innovation in a way that may be more effective in achieving the stated aims of the draft Bill. For example coordinated effort by leading organisations, including the GMC, to raise the profile and importance of innovation; encouraging medical students and doctors in training to participate in research and supporting those wishing to pursue clinical academic careers; highlighting the resources available to support not just doctors but nurses scientists and others involved in seeking new solutions to important challenges in healthcare; and supporting the emergence of centres of excellence to help achieve sustainable change and spread knowledge gained from innovation for the benefit of greater numbers of patients and their families. We will continue to work with other organisations to promote responsible innovation to improve patient care.