16 February 2010

Council

General
Medical
Council

Regulating doctors
Ensuring good medical practice

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To consider

GMC Affiliates

Issue

1. Next steps following the publication of the independent evaluation report of the GMC Affiliates Pilots.

Recommendation

2. To agree that we undertake further piloting of GMC Affiliates within the Revalidation Pathfinder Pilots and to expand the pilot in Scotland (paragraphs 23-47).

Further information

3. If you require further information about this paper, please contact us by email: gmc@gmc-uk.org or tel. 0161 923 6602

Background

4. The development of GMC Affiliates corresponds to Strategic Aim Five of the 2010 Business Plan, which states that we will develop more effective relationships with delivery partners in order to achieve an integrated approach to medical regulation in the UK.

5. An important recommendation of the Government White Paper *Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century* concerned establishing a network of GMC Affiliates at a regional level. The White Paper built on earlier recommendations in Sir Liam Donaldson's report, *Good Doctors, Safer Patients.*

6. The White Paper envisaged that GMC Affiliates would form part of a new 'Tackling Concerns Locally' architecture for dealing with concerns about doctors involving:

   a. Regional Medical Regulation Support Teams (RMRST): RMRSTs would operate at a regional level, providing a forum for medical directors and others to discuss medical poor performance and fitness to practise issues.

   b. Responsible Officers: the Responsible Officer would be a new role providing a focus to strengthen local clinical governance and provide a conduit for information exchange with the GMC on revalidation and fitness to practise issues.

   c. GMC Affiliates: affiliates would provide support, advice and guidance to employers and the commissioners of the services of doctors in managing concerns about doctors.

   d. Recorded Concerns: to provide a facility for recording concerns at a lower threshold than would normally warrant referral to the GMC for consideration under our fitness to practise procedures.

7. Following the publication of the White Paper, the Department of Health (England) set up five working groups to take forward developments arising from the White Paper. One of those groups was the 'Tackling Concerns Locally' Working Group, chaired by Dr Jenny Simpson, the Chief Executive of the British Association of Medical Managers. A sub-group, chaired by Paul Philip, was established to advise on the piloting proposals.

8. The Affiliates Sub-Group developed a model for piloting. The sub group included representatives from the BMA, the Locum Doctors' Association, NHS Trusts, the independent sector, defence organisations, Royal Colleges, patient groups, the National Clinical Assessment Service (NCAS), the Council for Healthcare Regulatory Excellence (CHRE) and Action against Medical Accidents (AvMA).

9. In May 2008 Council agreed proposals for piloting GMC Affiliates that, broadly speaking, followed the following criteria:

> a. The proposed arrangements should support local clinical governance in the NHS (particularly through the development of the Responsible Officer role).
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> b. The Affiliate role would not extend the GMC's regulatory authority (through our fitness to practise procedures) to a local level.
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> c. The presence of GMC Affiliates locally should help deflect complaints about doctors to where they can best and most speedily be dealt with at a local level.
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> d. The proposed arrangements would ensure that we continue to take timely and decisive action, where necessary, in order to protect the public in appropriate cases.

10. The proposal agreed by Council in May 2008 was significantly different to that contained in the White Paper. In particular, it focused heavily on developing the relationship between medical directors (as responsible officers) and the GMC, through affiliates. The rationale was to assist and support medical directors and local clinical governance in doing their job, not usurping it. The Health and Social Care Act 2008 does not contain any specific provisions regarding GMC Affiliates. It does, however, include a number of provisions for the introduction of responsible officers.

11. In autumn 2008 we initiated two GMC affiliate pilots – one in North London, the other in West Yorkshire. The North London pilot covered three PCT areas (Camden, Enfield and Haringey) and the West Yorkshire pilot covered five PCT areas (Bradford and Airedale Teaching PCT, NHS Calderdale, NHS Wakefield and District, NHS Leeds and NHS Kirklees).

12. The pilot areas were significantly different with West Yorkshire covering a mix of urban and rural communities while the London one covered a dense urban population. Both included medical directors from the NHS and the independent sector, although in West Yorkshire the independent sector was much smaller. The deaneries were involved in both areas and represented on the regional groups. The pilots ran for 12 months.

13. Both pilots were based on the model of pairing a medically qualified and a non-medically qualified GMC Affiliate. Three of the affiliates were GMC staff (including a medical case examiner, and two senior staff from the Fitness to Practise Directorate) and the other was a doctor employed by the Strategic Health Authority.

Aims of the pilots

14. The aim of the pilots was to establish whether it was possible to bridge the gap between national and local regulation and provide faster, more effective resolution of complaints and concerns about doctors in England.

15. We also wanted to clarify and develop the relationship between medical directors and GMC Affiliates to facilitate discussion about poorly performing doctors and to provide the medical directors with a more supportive environment. The pilots also explored the potential role of regional teams (RMRSTs) and the data they would need to support their work. The RMRSTs were mainly engaged in looking at major issues and trends using aggregate data rather discussing specific cases.

16. The pilots did not deal with revalidation issues, on the basis that it was too early in the development of policy on revalidation.

The role of GMC Affiliates

17. In the pilots the roles of the Affiliates were developed using the criteria in paragraph nine above. In particular, we were keen to ensure that they should not be seen to extend the GMC's regulatory responsibilities into areas that rightly remain the responsibility of local employers.

18. The affiliates provided advice and support on handling individual cases and related matters as well as on more strategic issues such as clinical governance, training and guidance. They were not directly responsible for casework handled as part of local processes. However, they had an important role in providing advice on the appropriate disposal of complaints and concerns, in particular, whether they should be dealt with under local procedures or referred to the GMC. They offered increased opportunities for discussion with medical directors and enhanced support in dealing with poor medical performance.

The role of the RMRST

19. The regional teams (RMRSTs) consisted of representatives of medical directors, locum and out-of-hours care agencies, SHA patient safety leads, the Deanery, the Care Quality Commission, the BMA, NCAS and complaints managers. In the North London pilot, all medical directors from the pilot area sat on the RMRST whereas in West Yorkshire it was a smaller group of medical directors from different practice settings. As a result the team in North London was larger.

20. The regional teams provided medical directors with an opportunity to share best practice and gain a better understanding of the roles of various agencies such as the GMC, the Deanery and NCAS. Meetings in both areas were well attended with a good level of contribution.

The modelling of Recorded Concerns

21. Although the concept of Recorded Concerns required further development, at the request of the DH(E), we agreed to carry out a modelling exercise within the GMC Affiliates Pilot to ascertain the likely usefulness of Recorded Concerns as an additional tool for medical directors in dealing with concerns about doctors. Part-way through the pilot, DH(E) changed the name of Recorded Concerns to Agreed Statements of Concern to reflect that fact that they would be the subject of agreement with the doctor.

22. The modelling exercise involved the medical directors indicating the number of cases where such a tool would be useful.

Discussion

Evaluation of the pilots

23. KPMG was commissioned by the DH(E) to evaluate the pilots. This was completed in three stages. First, they conducted baseline interviews to establish the perceived gap between local complaints processes and national regulatory systems.

24. Secondly, they ran mid-term interviews with key interest groups to establish views on each of the pilots, resulting in a mid-term report in April 2009. Finally, there were further interviews with key interest groups at the end of the pilots. They also developed a model for costing the pilots and provided indicative costs for a national roll-out.

Summary of Evaluation Report Findings

25. The Final Evaluation report of the GMC Affiliates Pilot was published in November 2009 and circulated to members on 2 December 2009. Their approach focussed on qualitative interviews with a wide range of local and national interested parties. A quantitative element focussed on the collation of data and cost modelling, to enable consideration of a wider national roll-out of GMC Affiliates.

26. The evaluation report covered four main areas: model and process, cost, data, reputation and perception. The broad conclusions were as follows:

a. Model and process: while there was significant support for the pairing of medical and lay affiliates, medical directors particularly valued access to expert fitness to practise knowledge. This tended to be provided by the lay affiliates who were senior GMC staff with experience of our fitness to practise work.

b. Cost: the cost of rolling out the model as piloted is likely to be substantial, and therefore a number of alternative models and modes of learning dissemination are discussed in the report.

c. Data: the report acknowledged that quality of local data varies, and this reflects wider issues around the use of data in assessing practitioner performance.

d. Reputation and perception: the pilots were considered to have enhanced the reputation of the GMC at a local level. They improved understanding, particularly among medical directors, of the GMC's thresholds for referral into our fitness to practise procedures and of our ethical guidance.

27. The KPMG evaluation concluded that there was very strong support for the GMC Affiliates model as piloted. This was in large part due to the calibre of the affiliates who took part in the pilots and their ability quickly to gain the trust and confidence of medical directors.

Outcome of the modelling of Agreed Statements of Concern

28. The feedback from modelling Agreed Statements of Concern was inconclusive. Although medical directors identified around ten cases in each site where an Agreed Statement of Concern might have been useful, it was impossible to say whether agreement with the doctor would have been possible. The Affiliates Sub-Group concluded that the modelling exercise had not moved the discussion much further forward and did not support the development of this concept at this point.

Feedback from medical directors

29. There was very strong support for the piloted model of GMC Affiliate Pilots from medical directors.

30. The pilot has helped to forge better relationships between the GMC and medical directors, who particularly valued access to the lay affiliate's expert fitness to practise knowledge. The opportunity to discuss individual cases on a confidential basis, prior to making a referral or taking action locally, was seen as a key benefit.

31. Medical directors felt that the affiliate scheme had resulted in better outcomes for doctors and patients, and faster resolution of individual complaints, with improved links between local and national handling of complaints.

Effectiveness of Regional Medical Regulation Support Teams

32. Those who attended the regional team meetings felt they benefited from the experience as a forum for discussion, and valued the opportunity to understand the perspective of different agencies on difficult cases and themes. However, among some of those who were not part of the teams there were some concerns about accountability and transparency of governance.

Alternative models

33. The report estimates that a national roll-out of the GMC Affiliates model as piloted would cost between £2.2 million to £4.6 million. It also sets out proposals which would be more cost-effective and suitable for national roll-out. These include implementing a regional structure, with a single non-medical affiliate, or using affiliates and the RMRST to assist in the roll out of wider regulatory reform.

34. Another option, which has been piloted in Scotland, would be to create a senior GMC fitness to practise case manager who would act as a 'named contact' for medical directors to discuss cases on an ad hoc basis. There is no RMRST in this model. This approach has been developed as part of an exercise between the GMC, the Chief Medical Officer for Scotland and the Scottish Association of Medical Directors to improve liaison between the GMC and medical employers in Scotland.

35. Anna Rowland met with the Department of Health, Social Services and Public Safety in Northern Ireland on 25 January 2010. Paul Philip is due to meet with medical directors from the seven local Health Boards in Wales in June 2010, and further meetings with medical directors from the Health Boards in Scotland will be held to discuss the pilots and the outcome of the evaluation report with a view to deciding how to take matters forward in the respective countries.

36. Following the pilot, the DH(E) is considering the possibility of commissioning some work with patient groups about how to reflect patients' views into local processes.

Next steps

37. The lesson from the pilots, according to the independent report and informal feedback from those involved, is that developing closer links between the GMC and medical directors provides clear benefits. The work of the affiliates led to significantly improved relationships between the GMC and medical directors, a significant enhancement of our reputation and more effective links with employers in dealing with concerns about doctors.

38. In Scotland, where we piloted the streamlined version described in paragraph 34 above we received similarly positive feedback on an informal basis.

39. The key issue is how we should now proceed and, in particular, whether there should be further investment to clarify the role that affiliates might play in supporting the introduction of revalidation.

40. We have had initial discussions with DH(E) about the outcome of the pilots. As a result we are proposing that the role of affiliates within the context of revalidation should be piloted for six months on a regional basis to coincide with the Revalidation Pathfinder Pilots.

41. The revalidation pilots were launched on 26 January 2010 and are being run by the Revalidation Support Team (RST) with support from DH(E) and an external evaluation team. Approximately 3,000 doctors will be involved at pilot sites which have been identified by RST. They include some that are well prepared as well as those requiring significant development so the variation in impact can be identified. Where possible pilot sites will test all components of the proposed system, although some will test specific components depending on local capacity.

42. In discussion with DH(E) we have identified two pilot sites where region-wide affiliates could be piloted:

a. A pilot co-ordinated by West Midlands SHA involving approximately 45 medical directors acting as responsible officers in turn reporting to a responsible officer at regional level. This pilot will specifically test the role of the Responsible Officer and their relationship with their own responsible officer at the SHA.

b. A collaborative pilot involving Yorkshire and Humber SHA, with the Deanery, involving primary care, secondary care and mental health and covering approximately 450 doctors, evaluating the impact of proposals for revalidation across the wide variety of circumstances in which doctors work. A key part of this will be testing the systems for appraisal.

43. The GMC Affiliates Pilot was based on a model of pairing a medical affiliate and a lay affiliate in each area. Within the evaluation report this model was supported by medical directors and referred to as a 'Gold Standard' but medical directors reported that what they particularly valued was access to the expert fitness to practise knowledge of the lay affiliates. On this basis we are proposing to pilot the appointment of a single lay affiliate with expert fitness to practise knowledge in each of the two pilot sites identified above.

44. We have asked DH(E) to pay for the pilots and we are currently developing a funding proposal. We estimate the likely cost to be in the region of £200,000.

45. If this proposal is agreed we will keep Council updated both on the development of Responsible Officers and on progress with the pilots. DH(E) is planning an independent evaluation of the Pathfinder Pilots which will involve an interim report half way through the pilot and a final report at conclusion. We will seek to include the Affiliate role in supporting revalidation within that evaluation process with a view to receiving feedback in the interim report. We will report to Council in October or December 2010 to reassess the position in light of the evaluation.

46. The role of affiliates in supporting revalidation will focus primarily on the tranche of doctors who fail to revalidate or where their revalidation is delayed as a result of outstanding concerns. This is likely to be a very small percentage of those undergoing revalidation but the assessment of these doctors is likely to use a significant proportion of our resource.

47. In discussion with the Scottish Government and the Scottish Association of Medical Directors, we also propose to go on piloting a streamlined version of the Affiliates model in Scotland to continue to assess the effectiveness of this model but more widely; in particular testing the provision of an annual study day to improve understanding of GMC Fitness to Practise processes and thresholds.

Recommendation: To agree that we undertake further piloting of GMC Affiliates within the Revalidation Pathfinder Pilots and to expand the pilot in Scotland.

Resource implications

48. We estimate that the two six month pilots on the Affiliate role in supporting revalidation as part of the Revalidation Pathfinder Pilots will be in the region of £200,000. We have asked DH(E) to fund the pilots and are in the process of preparing a proposal seeking that funding.

49. The provision of a dedicated resource to continue the pilot in Scotland will be approximately £120,000.

Equality

50. An Equality Impact Assessment was produced for the pilot and reviewed regularly by the project steering group.

51. Doctors who attended a GMC/BME forum on 29 May 2009 expressed support for the GMC Affiliates Pilot model as lessening their concerns about the introduction of the Responsible Officer role. In particular, the independence of the affiliates from local processes was felt to be a key benefit.