AvMA'S RESPONSE TO THE GMC CONSULTATION

Revalidation: the way ahead

June 2010

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Response from Action against Medical Accidents

About AvMA

Action against Medical Accidents (AvMA) was originally established in 1982. It is the UK charity campaigning for patient safety and justice. AvMA specialises in advice and support for patients and their families affected by medical accidents, via its Help-Line, through individual case work and in providing specialist advocacy. Since its inception, AvMA has provided advice and support to over 100,000 people affected by medical accidents, and succeeded in bringing about major changes to the way that the legal system deals with clinical negligence cases and in moving patient safety higher up the agenda. AvMA also maintains a register of expert witnesses and supports solicitors who act for claimants in clinical negligence claims, providing education, advice and panel accreditation.

Executive Summary

AvMA welcomes the fact that progress is being made towards introducing revalidation but it is evident from the document that there is still a considerable way to go in terms formulating some of the key principles and practicalities of how revalidation will work in practice. This is particularly true in relation to practitioners who work outside mainstream managed environments.

As a patients' organisation, we will necessarily focus on this consultation from the patients' perspective and whether revalidation as proposed will lead to greater protection for patients and higher standards across the profession.

In reviewing the document, there were a number of areas arising from the proposals where we felt it fell short in terms of putting patient safety at the centre of the process:

A key issue related to the proposal to roll out revalidation to those organisations which already have good systems of clinical governance and appraisal in place. It is perhaps self-evident that well-functioning organisations that meet these criteria are those that are more likely to have good self-regulation and where patients' interests are going to be better protected. On the other hand, it appears that those organisations that do not have good systems of clinical governance and appraisal in place are in effect going to be at the end of the queue as well as those individual doctors who do not work within mainstream managed environments. The public might reasonably anticipate that the converse would be the case. However, because revalidation rests heavily on local appraisal, there is clearly an inherent problem in introducing revalidation where local procedures are not working effectively. This does beg the question of what happens in the interim whilst organisations are developing their systems on the basis that poorly performing doctors often work within poorly performing organisations. This would the suggest the need for interim

or alternative arrangements to target poorly performing organisations as well as the 'higher risk' groups of doctors working outside managed environments. Revalidation is about protecting patients and improving standards and it would undermine the process if it very obviously fails to achieve that goal by targeting the lower risk organisations first.

The role of patients and the public is largely ill-defined other than in prescribed roles such as patient questionnaires. AvMA would like to see a far greater role for patients and patients' organisations both at a strategic level as well as at local level through direct involvement in feeding into and monitoring the revalidation process.

Revalidation is heavily reliant on effective local systems. It is important to learn from some of the catastrophic healthcare failures that have come to light in recent years, particularly where local systems have broken down. The GMC and Responsible Officers will need to work alongside other organisations such as the Care Quality Commission, the Ombudsman and the National Clinical Assessment Service to ensure local systems are working effectively. The GMC itself has a wealth of information available to it from fitness to practise cases which it can utilise in ensuring revalidation is appropriately targeted whilst minimising the burden on the majority of doctors. It also needs to be sufficiently flexible in approach that it can ensure loopholes can be quickly closed and to accommodate the wide range of environments and roles doctors are employed in.

An important concern from a patients' perspective is assurance of standards and transparency: that a GMC licence denotes a doctor is meeting core standards of practice and is practising to currently accepted standards in his or her specialty. A significant area that was not addressed in any great detail in this document is how the proposals will work in relation to doctors from the EU. In other words, what assurances can patients have that EU doctors practising in the United Kingdom will be meeting the equivalent standards of doctors who have qualified and trained within the UK. There have been a number of cases over recent years that have highlighted how the current inability of the GMC to apply the same standards to EU doctors as to UK trained doctors is undermining the validity of GMC registration and in particular the specialist register. It is therefore essential that in tandem with developing revalidation, the wider issue of a lack of equivalence of standards/training across the EU is addressed.

If revalidation is to work, we need to develop well resourced systems for dealing with those doctors who are not meeting the required standard. The alternative is that revalidation becomes an exercise of significant compromise rather that an effective system for protecting patients through supporting doctors to recognise and address weaknesses in their practice.

Consultation questions

Question 1: Do you agree that revalidation should be based on a single set of processes for evaluating doctors' performance in practice, rather than split into the separate elements of relicensing and recertification?

Yes but providing this still allows for a robust assessment of a clinician's specialist practice. We recognise that if the system of revalidation becomes over-burdensome, it will also become less effective. However, there needs to be transparency in what revalidation means and what a doctor is being recertified in. For example, an historic certification or entry on the specialist register in an area in which a doctor has not practised for many years, needs to be clearly 'historic' so there is no room for confusion. Combining the two processes of recertification and revalidation should have the same end result in that patients and employers can be confident that a doctor who has been licensed to practice is meeting both core generic standards as well as the individual specialty standards. This needs to be supported by consistently applied standards.

The document also makes limited reference to how licensing will apply to EU and overseas doctors. It could be argued that the current requirement for the GMC to allow EU doctors to register with the GMC without undertaking additional checks has resulted in an undermining of the UK's system of regulation including entry on the specialist register. We have had the recent case of Dr Ubani where those employing him assumed, rightly or wrongly, that an entry on the GP register meant he was fit to practise in that field. The GMC stamp of approval needs to mean just that and there should be no room for confusion. If this is not addressed, then the validity of revalidation will be equally undermined. Therefore the development of revalidation should go hand in hand with ensuring all doctors on the GMC specialist register and GP register are meeting the same specific standards. These standards should be set at the highest practical level to ensure that patients can be assured of a high quality of care rather than lowering the bar to accommodate practitioners at the lower end of the spectrum who potentially represent a risk to patient safety.

Question 2: Do you agree that revalidation should be based on a continuing evaluation of doctors' performance in the workplace?

Yes on the basis that this is the most pragmatic approach but recognising that a system of revalidation based on local appraisal is not without its problems. Continuous evaluation is important on the basis that a five-yearly snapshot of a doctor's practice is unlikely to provide reliable evidence and if problems are identified, these need to be addressed in a timely fashion.

For those individuals working in environments without an appropriate management or appraisal structure, the proposals still require a considerable amount of work. This group arguable includes those practitioners most in need of support and scrutiny. If practitioners are not working in a mainstream setting, it is unclear how they will produce the quality and quantity of evidence equivalent to that required for mainstream practice. The concern is that this would potentially mean they will either

not meet the requirements for revalidation or the standard required will in effect be set much lower. Unfortunately, because revalidation as proposed relies almost entirely on locally based procedures, it means that those individuals who already fall outside managed clinical environments, will also not fit within the revalidation proposals as described. There would therefore be an argument for looking at those groups separately and potentially taking a very different approach to revalidation on the basis that in trying to make one process fit all situations, it may prove least effective in those areas where regulation is most required.

We share with many other groups a continuing concern that the traditional appraisal process has a very different function to that required for revalidation. There is the potential for conflict with employers (both NHS and the independent sector) having their own vested interests in the process which may well conflict with the needs of revalidation. For the individual doctor, there is the potential threat that not only their current employment but their license to practise may be at risk if they express criticisms even if those criticisms are valid and in the interests of patient safety. From the patients' perspective, what confidence will patients and the public have in the revalidation process if individual organisations operating the local appraisal procedures are themselves revealed to be poorly performing or are the subject of significant criticism?

Question 3: Do you agree with the proposals for dealing with the most common situations where a Responsible Officer may not be in a position to make a positive recommendation?

Yes.

Question 4: Do you agree that the Colleges and Faculties should not be directly involved in the recommendations made by the Responsible Officer to the GMC?

Yes. The Colleges and Faculties clearly have an essential role in terms of setting speciality standards and in advisory role. With time, their role may evolve and we would anticipate that they would play a significant part in areas such as remedial intervention.

Question 5: If so, what do you think their role should involve? Please tick one or more of the following options:

Setting standards and defining specialty information - Yes
Advice and guidance for appraisers - Yes
Advice and guidance for Responsible Officers - Yes

Question 6: Do you agree that for trainees, successful progression through training should be the means of securing revalidation?

This would appear to be the most pragmatic approach but subject to how the ARCP is further developed to meet the requirements of revalidation including

patient/colleague feedback. Revalidation is a different process to assessing ongoing training and it is important not to damage one in the pursuit of the other.

Question 7: Do you agree with our proposals for the revalidation of doctors with no medical practice of any kind?

No. If a doctor has no medical practice of any kind, then they cannot be properly assessed against the core or specialty standards. To revalidate doctors in these circumstances would add confusion and potentially undermine revalidation as a whole. It would be illogical to set a high bar for the majority and then let through a minority on the basis of the least evidence. This does not mean that there couldn't be an alternative process with an alternative to granting a licence to practice but there does need to be a clear and transparent distinction between doctors who have been assessed as clinically up to date and competent and those that are no longer in clinical practice.

Question 8: Do you agree that the list of registered and licensed medical practitioners should indicate the field of practice on the basis of which a doctor has secured revalidation?

Yes. This is again about transparency. For revalidation to be meaningful, and if doctors are being assessed on the basis of their current area of practice, then the outcome of revalidation should clearly indicate the basis on which they have been assessed.

Question 9: Do you agree that, for the purposes of revalidation, the Good Medical Practice Framework is an appropriate basis for appraisal and assessment?

Yes. This should be subject to ongoing review to ensure it is keeping abreast of developments in medical practice and clinical roles and changes in healthcare provision in general.

Question 10: Do you have any further comments on the proposed use of the Good Medical Practice Framework?

As discussed elsewhere, the assessment of doctors working outside mainstream clinical roles against the Good Medical Practice Framework is likely to prove more difficult. Whilst most doctors will fall within the GMP Framework, for those that do not, there is a risk that they will end up being subjected to a 'short-form' version of the appraisal process and potentially achieve revalidation on a lower standard of evidence. To avoid this, consideration needs to be given to alternative frameworks and means of ensuring equivalence in the quality of evidence used as the basis for revalidation.

There will be other situations where doctors are unable to provide all the evidence required, and again, consideration will need to be given as to how this is addressed

whether through conditional licences or allowing for further interim assessments during the five year cycle to allow further evidence to be submitted. The underlying principle is patient safety and ensuring that revalidation operates fairly and consistently in the interests of both patients and the profession and that the 'difficult cases' are not in effect passported through simply because they do not fit the standard appraisal/revalidation route. There needs to be a common sense approach that avoids being process driven.

Question 11: Is the overall approach to the development of standards and supporting information for revalidation reasonable? If not, what else is necessary?

We do not know to what extent there is a degree of equivalence between the standards set by the different Colleges and Faculties. The role of the Colleges and Faculties is clearly central to establishing speciality standards but it is yet to be seen how this will work in practice at local level and whether differences will be found both in the standards required by different specialties and the way in which those are interpreted at local level. A key concern from a patients' perspective is the risk that poorly performing organisations will fail to identify underperforming clinicians and that they will in turn achieve revalidation on the basis of a much lower standard. If patient safety is accepted as the underlying principle, then there needs to be an effective system for identifying those organisations that are failing and an alternative appraisal/revalidation route for doctors working within those organisations.

Outcome data and patient feedback including complaints should form a core part of the data used. You cannot undertake a valid assessment of the quality of a service without including the users of that service in the assessment. It should be remembered that patients not the professions were at the forefront of the patient safety agenda. As has been seen recently with the Mid Staffordshire NHS Trust, the Trust's view of its service provision bore very little relation to the standard of care being experienced by its patients - but they were not being heard. It is essential that mechanisms for patients to be involved and heard both at local and national level are re-established.

Question 12: Is the supporting information proposed by the Colleges and Faculties meaningful, practicable and proportionate for the majority of doctors in clinical practice?

As set out above, the real challenge is going to be dealing with the exceptions, the individuals who fall outside of the mainstream or who are unable to provide a complete portfolio of evidence. As suggested previously, this is where conditional licenses or interim reviews may provide part of the solution.

Question 13: Do you agree that these are the appropriate principles to guide doctors' Continuing Professional Development (CPD) activity in relation to revalidation? If not, what alternative approach is required?

CPD has to be meaningful. Patients want to be assured that the doctor treating them is up to date with current treatment options, is skilled in their use, and is not using out of date or proscribed treatments. This would suggest the need for some guidance on 'essential' training from the Colleges and Faculties.

Employers have an equal responsibility to support CPD, the risk being that with the future financial restraints facing healthcare organisations, the time and money allowed for CPD will be under threat, providing one example where there is a potential for a conflict of interest and/or complicity between the employer and the doctor seeking revalidation.

Question 14: Do you agree with our approach to patient and public involvement in revalidation? If not, what other arrangements would you suggest?

Under the original proposals for revalidation, GMC affiliates were to provide the main vehicle by which there would be genuine and effective lay involvement and oversight of the process. The consultation document suggests a much reduced role for lay involvement. To attempt to prescribe the role of patients to 'completing patient questionnaires' is to ignore the wealth of experience that users can bring to the development, implementation, and oversight of revalidation. This is of real concern. The current model of revalidation based on local systems of appraisal has vulnerabilities in terms of mutual self-interest/conflict of interest between employer and doctor, as well as variations in how the standards will be interpreted, particularly in those organisations that are underperforming. Independent lay involvement at local level will be key to counteracting the kind of issues that risk undermining the validity of revalidation.

It should be remembered that historically it has very often been patients who have raised concerns about individual doctors, not the profession itself. Patients have been very much at the forefront of the patient safety agenda. Unfortunately, over recent years there has been a systematic dismantling of mechanisms for engaging patients and the public both locally and nationally. The GMC itself abolished its Patient and Public Reference Group in 2009.

For effective patient and public involvement, it is important to include both individuals with experience either through membership of local and national patient groups/organisations to provide specialist expertise as well as individual users of local services. This should specifically include those who have experienced service failure. The argument is often used that patient groups come with 'vested' interests. However, these 'vested' interests often arise because the needs of a particular group of patients or users are being ignored.

The consultation document would suggest that a great deal more work needs to be done to ensure an effective role for patients and the public in revalidation.

Question 15: Do you agree that GMC Principles, Criteria and Key Indicators for Colleague and Patient Questionnaires in Revalidation are appropriate for evaluating these types of questionnaires for revalidation?

The principles appear reasonable but as set out in question 14, patients must be involved from the earliest stages of development as opposed to being consulted after the event when considerable resources have already been invested.

Question 16: Do you agree that doctors should be required to participate in colleague and patient (where applicable) feedback at least once in each five year cycle?

As a minimum, yes. However, it is probably more effective to encourage continuous feedback from users as well as ensuring that complaints, patient safety incidents, serious untoward incident reports and other outcome measures are included as part of the annual appraisal. In relation to patient safety incidents, a key issue for assessment is the extent to which a practitioner can demonstrate that they have been able to incorporate what they have learnt into their professional practice.

Question 17: Do you think that there should be a mechanism for making sure that colleague and patient questionnaires comply with our criteria for revalidation?

Yes – to avoid duplication and to ensure that as far as is possible, bearing in mind the very different relationships different specialties have with their patients, some equivalence in the data produced.

Question 18: Do you agree that revalidation should be introduced initially in areas and organisations where local systems are developed and sufficiently robust to support the revalidation of their doctors?

No, from the point of view that there would seem to be a certain illogicality in targeting those doctors who are working in well managed environments whilst leaving doctors in potentially higher risk groups to be the last to be subject to revalidation. Every effort should be made to minimise the delay before the process is rolled out to different groups but with a particular focus on those areas that are identified as being higher risk e.g. locums.

Question 19: Do you agree with our proposed approach for the initial roll-out of revalidation? If not, what alternatives do you suggest?

There are significant gaps in the detail of how revalidation will work in practice and it is clear that there is considerably more work required on how revalidation will work for those doctors working outside mainstream managed healthcare environments. In the meantime, pilots are still being set up to test the various processes. The timescale for the introduction of revalidation of 2011 is therefore potentially ambitious. However, there is the risk that this will still be under discussion in ten years time and it could be delayed indefinitely if the aim is to introduce the ‘perfect

system' on day one rather than an evolving process as lessons are learned and the process refined. As set out above, a key focus should be those groups that are identified as higher risk.

Question 20: Do you agree that a deadline should be set for organisational readiness for revalidation?

Yes. The proposals for revalidation have been under discussion for a decade. As set out above, we would be concerned if doctors working in organisations that were struggling to meet the standard were put to the back of the queue for inclusion in revalidation. Notwithstanding the practical difficulties of revalidation in poorly managed environments, patients and the public would reasonably anticipate that revalidation would be targeting the high risk groups first as opposed to those individuals working in well managed organisations.

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