AvMA's Response to the GMC's Consultation on the Draft Licensing and Revalidation Regulations

1.1 Action against Medical Accidents (AvMA) was originally established in 1982. It is the UK charity specialising in advice and support for patients and their families affected by medical accidents. 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. The legal reforms of Lord Woolf in the clinical negligence field and the creation of agencies such as the National Patient Safety Agency and the Healthcare Commission have followed after years of campaigning by AvMA.

Introduction

2.1. AvMA welcomes the introduction of a system of revalidation and licensing for doctors as a means of protecting patients and raising standards within the profession. However, the current proposals as set out in the policy framework, guidance and regulations fall short in terms of providing an assurance that revalidation is going to fulfil its intended purpose. There are significant gaps in the detail of how revalidation will work in practice and the contributions required of the various partners in the process, and it is very much in the detail that revalidation will stand or fall.

2.2. AvMA's primary concern relates to the apparent delegation, if not abdication, of responsibility for large parts of the revalidation process to external bodies. It is accepted that revalidation will need to be achieved in partnership but as the body charged with the responsibility for raising professional standards, the GMC must be seen to be driving the process and ultimately being accountable for all aspects of revalidation.

2.3. From the original proposals of a GMC led process, there now appears to be an over-reliance on locally based appraisals as the primary pillar underpinning revalidation. The understanding was that the role of appraisals, with the limitations of a locally based procedure, would be one of contributing to the body of evidence required for revalidation and that ultimately, the doctor would be subject to external scrutiny based on GMC approved standards. The present appraisal-based model of revalidation is likely to lead to wide variations in the standards required of individual doctors to achieve revalidation.

2.4. For appraisal to have any significant role in revalidation, it would be essential to have in place a well-developed system and culture of clinical governance, agreed professional standards against which practitioners can be assessed, and patient centred quality assurance. In relation to standards, whilst some commendable

work has been done by the various colleges in developing specialty specific standards, this is still at a relatively early stage and there is no clarity as to how such standards could be applied consistently at local level and to individual doctors.

2.5. A list of organisations has been included in the guidance as 'likely to fall within the definition of GMC approved environment'. The proposal that all NHS bodies and a large proportion of the main independent providers would potentially fall within this category would be a significant if not fatal flaw in the process. A 'GMC approved environment' should be just that - an organisation that has been audited and assessed against set standards and been granted approval. The present proposals suggest that any organisation which can demonstrate they have procedures for clinical governance and appraisal are likely to be deemed as having 'approved' status regardless of how these procedures operate in practice.

2.6. Revalidation has the potential to represent a groundbreaking development for the GMC in terms of public protection and renewing confidence in the profession and professional regulation. AvMA's concern is that from a GMC led process, the current model for revalidation appears to be one where the GMC is in danger of being perceived as a passive repository of a data collection process over which they have limited control and with accountability fragmented. The GMC must retain full ownership of revalidation and be fully accountable for its operation. The alternative is that in the post-Shipman era, we are looking at a completely new model of professional regulation where the role of the GMC is greatly diminished. The GMC also needs to be clear about what is required from its partners in the process, striving not for the minimum acceptable standard but that which will ensure patients can have confidence that a license to practise equates with the highest principles of patient safety and professional standards.

2.7. AvMA recognises that revalidation poses enormous challenges not just to the profession but to our systems of healthcare as a whole. A robust system of revalidation would for the first time expose the true extent of the wide variation in professional standards and competency that exist. There may therefore be some concern that whilst the majority of the profession do practise to a good standard, if we were to remove from our workforce or restrict the practice of all those doctors who were identified as performing below an acceptable standard, we would be struggling to find sufficient doctors to maintain our services. However, if we set the revalidation bar too low, then it will have little if any credibility and will only further damage the profession and the GMC as regulator.

2.8. An essential element of revalidation is establishing and setting the standards against which doctors will be assessed, and the body of evidence that doctors will be required to produce. This is at the core of revalidation. It will not only benefit patients in terms of being assured of consistency in standards but will also provide a framework and benchmark for doctors to help and support them to

ensure their practice continues to be in accordance with current professional standards.

2.9. It is difficult to comment on the specifics of the regulations and guidance on the basis that our main areas of concern relate to the underlying principles of the policy framework. We will therefore address the regulations and guidance in the context of the policy framework.

Policy aims of revalidation

3.1. The purpose of revalidation as set out in the guidance is to ensure that patients can have confidence that their doctors are 'competent' and that they are 'up to date and fit to practise'.

3.2. The validity of the revalidation process depends on where the benchmark for competency is set and whether we are aspiring to the highest standards as opposed to a standard which will allow the majority of doctors to achieve revalidation. The risk is that this could become an exercise in significant compromise and inconsistency of the standards expected. The standards expected of practitioners for revalidation should remain as high as the current standard for the relevant Royal College.

3.3. In terms of the three broad policy aims, AvMA would like to see a more explicit expression of a commitment to raising standards. Perhaps consideration should be given to recognising in some form, those practitioners who are practising at the highest standards.

Appraisals

4.1. It is apparent from the documentation that appraisal represents one of the mainstays of the revalidation process. Whilst appraisals will become an essential part of local regulation and supporting pracititioners within the workplace, there is clearly a gap between what appraisal is designed to do and what is required if revalidation is to be meaningful in protecting the interests of patients. The concern is that too much reliance is being placed on the appraisal system as underpinning the revalidation process and that the areas that may be of most concern to patients, the quality and safety of that doctor's treatment, will not be addressed. If the appraisal route is to be included in the revalidation process, then it has to be supplemented by external scrutiny of a doctor's practice based on specified standards.

4.2. It is also of concern that the GMC has a lack of direct control over the appraisal process. For appraisal to have a valid role in revalidation, it should be by way of delegation of responsibility for this part of the revalidation process rather than relinquishing control to local service providers. The NHS is increasingly fragmented, including the diverging practices and policies following devolution

and it is essential that consistent standards can be applied within all healthcare settings across the United Kingdom.

4.3. An essential part of the appraisal process will be an examination of adverse outcomes. It is important to establish that a practitioner has sufficient insight to identify and acknowledge adverse outcomes, the part they played in it, whether and how it could have been prevented and of particular importance, how the needs of the patient and relatives were met. Whilst the identification that an adverse event has taken place might seem straightforward, from the patients' perspective, the hardest hurdle they often have to overcome is obtaining an acknowledgement that something has indeed gone wrong. This is not just a matter relating to the individual doctor or doctors, but the organisations in which they practise. We need to look at how adverse outcomes which have not been identified by the practitioner or the employing organisation can be detected and be subject to scrutiny under the revalidation process.

Appraisal and Approved environments

4.4. As indicated in the introduction, AvMA believes that if local appraisal is to play a significant role in revalidation, 'approved environments' should be precisely that rather than a blanket approval being granted. Having procedures in place is one thing, how they are applied in practice is quite another.

4.5. The concept of approved environments raises a number of questions: Is there going to be a process by which 'approval' can be removed? Will the GMC take a lead on quality assurance of the appraisal process? What accountability will there be for 'approved environments'? If seriously under-performing or potentially dangerous doctors attain revalidation who will be held accountable - the employer, the colleges, the DH or the GMC?

4.6. It would also be important to consider how we can counteract the conflicts of interest that may arise between practitioner and employer, and employer and the certification and revalidation process. It is AvMA's experience that many poorly performing practitioners are working within poorly performing organisations and there is often a lack of insight on the part of both the practitioner and the employing organisation and/or a degree of complicity in condoning or ignoring poor practice. This is often most clearly demonstrated in the way in which employing organisations respond to clinical complaints. In addition, there have been sufficient examples coming before the GMC fitness to practise procedures of doctors who have been employed both within the NHS and the independent sector who have continued to practise with relative impunity over many years, to demonstrate that a significant change in culture and practice is required before patients can be assured that local appraisal systems are going to produce consistent and reliable evidence for revalidation.

4.7. The alternative is that in the post-Shipman era, we are looking at a completely new model of professional regulation where the role of the GMC is greatly diminished.

4.8. An NHS Trust which has difficulty in filling its medical posts may be tempted to ignore under-performance and on the converse, doctors may feel pressured to remain silent about problems in service delivery if this may directly affect their revalidation i.e. is a problem doctor one who complains about failings in service provision? Will trusts be concerned about the legal ramifications if a doctor's appraisal could lead to the loss of the doctor's license to practice?

4.9. The appraisal process must be quality assured with patients and the public playing a core role as set out in the original plans for revalidation.

Patient and Public Involvement

5.1. Throughout the 1990s, patients and relatives who raised concerns about their medical care went from largely being ignored to being increasingly vilified. Attention was diverted away from the issue of avoidable medical harm, to blaming patients for having unrealistic expectations of achievable outcomes resulting in scaremongering about an alleged tide of american style litigiousness and creating a culture of defensive medicine. The reality is that the enormous courage of the small numbers of patients who had the wherewithall to challenge poor standards has been the driving force behind the whole patient safety agenda. From AvMA's inception in 1982, the one thing that has consistently been at the top of the agenda for patients and relatives who have experienced medical harm is the need to prevent the same thing happening to anyone else - the very essence of patient safety. Unfortunately, now that patient safety and the need to regulate and raise standards has finally been recognised, the central role that patients and relatives played appears to have been largely forgotten. If we want effective systems of regulation, we must ensure that patients, particularly those who have experienced medical harm and whose primary motivation is patient safety, are heard.

5.2. Therefore, AvMA would strongly argue that the voice of patients and the public should be central to the process of revalidation. Under the present proposals, it is unclear how and where patients have a place in revalidation and/or appraisal other than in a somewhat peripheral way through patient questionnaires and complaints ‘data'.

5.3. In the original proposals for revalidation, complaints documentation was to be included in the folder of evidence. AvMA would want assurances that this will still be included.

Independent sector

6.1. The independent healthcare sector as a whole, notwithstanding that there may be some emerging examples of good practice, has not had a reliable history in terms of clinical governance. The evidence for this can be taken directly from the patient experience of the handling of clinical complaints. If one is looking to quality assure clinical governance and assess how patient centred the approach to care is, whether in the independent sector or the NHS, there is no better place to start than with an examination of an organisation's handling of complaints and complaints investigations. AvMA's experience of the approach taken by the independent sector in dealing with complaints, would suggest that there would need to be a significant change in culture, practice and regulation before the independent sector would be deemed a reliable contributor to the revalidation process.

6.2. The independent sector also has a poor record in terms of patient and public involvement. It is notable that patients groups or representatives do not appear to have had a significant role, if any, in the development of the BMA/Independent Healthcare Forum Appraisal process.

Doctors working outside of approved environments

7.1. Although practitioners who fall within this category are potentially those who require the tightest regulation, this appears to be one of the weakest areas of the revalidation process. It potentially amounts to a 'self-certification' process. AvMA would recommend that these practitioners should be subject to direct revalidation by the GMC itself in conjunction with the colleges.

Doctors trained overseas

8.1. With our health services increasingly reliant on recruiting practitioners from overseas, it is important that licensing and revalidation will apply consistently to all practitioners. There is insufficient information contained within the documents to determine how this will be achieved and how we are going to work with other jurisdictions to ensure consistency in standards and protection of patients.

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