RESPONSE TO WELSH ASSEMBLY GOVERNMENT CONSULTATION ON

"PUTTING THINGS RIGHT"

APRIL 2010

About AvMA

Action against Medical Accidents (AvMA) is the UK charity for patient safety and justice and has a strong commitment to pursuing its objectives in Wales. Established in 1982, AvMA specialises in advice and support for patients and their families affected by medical accidents, via its Help-Line and through individual case work. 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 is therefore ideally placed to comment on these proposals from the patient's perspective. AvMA enjoys a constructive relationship with all key stakeholders in Wales and is pleased to have been able to make a significant contribution to the planning that led up to these proposals.

Executive Summary of AvMA's response

AvMA welcomes the policy intentions behind the measures set out in the 'Putting Things Right' consultation document. In particular we welcome the intention to be open, to investigate concerns thoroughly and as soon as possible, to learn lessons and to take remedial action including an offer of financial compensation if appropriate.

However, there are significant gaps in the proposals as they are currently set out, which cause us great concern. In particular:

- The proposals only relate to where 'concerns' are raised. However, a patient or their family may not be in a position to raise a concern if they are not informed that something untoward has happened in the course of their treatment. Sadly, it is sometimes the case that this happens. There have for a number of years been calls for a statutory duty of candour in the NHS (also known as 'Robbie's law'). The 'Putting Things Right' initiative provides the ideal opportunity to introduce such a duty in a way which is entirely consistent with the overall policy intention, and with the added benefits of commitments to be fair and supportive to staff as well. This would be a massive step forward in developing an 'open and fair' patient safety culture. A simple amendment to the regulations or additional clause should be introduced to make it a requirement to report a patient safety incident which has caused harm or may lead to harm to a patient. This would constitute a 'concern' under the arrangements. We believe that without this vital element not only will an excellent opportunity be missed to develop the desired culture of openness, but doubt will be cast on the credibility of the initiative itself.
- The availability of independent specialist advice from an early stage is vitally important if patients are to be more than passive recipients of the process. Often they will need help to be able to take part on a more informed, level footing. We understand that it is the intention to provide for this kind of advice and support by funding Community Health

Councils and AvMA (see impact assessment), this commitment needs to be reflected in the regulations.

- As currently worded, the regulations do not provide a means of resolving cases where there is a dispute as to whether there is eligibility for redress. Nor do they detail the level of advice and representation to be provided so that advice can be given about the level of compensation. This is contrary to the recommendations of the working party, which envisaged a process similar to the 'Speedy Resolution' scheme, whereby an independent medical expert may be jointly instructed by both sides in the dispute, to resolve such cases. Without the benefit of legal advice and independent medical advice to examine or challenge decisions made by NHS bodies, the scheme is unlikely to enjoy public confidence.
- Patients who might take legal proceedings should not be excluded from the scheme because they are considering this or taking advice.
- The limitation holiday should start when a concern is raised and should be extended if the patient is being advised under the scheme.
- Until the scheme has become established and tested the cap on financial compensation under the scheme should be £25,000 (including both general and special damages) unless both parties agree otherwise.
- In the spirit of openness, an investigation report should be made available to patients even if there is a decision not to offer redress.

If these issues are not addressed the proposals are unlikely to be workable or enjoy public confidence.

Detailed Response

Being Open

A 'Duty of Candour' should be included in the regulations requiring openness and honesty with patients and their families when things go wrong. There should be a duty on anybody employed by the NHS in Wales, or contracted to the NHS, to notify a concern. Where harm has been caused the patient must be informed if a concern has been raised. The new clause would introduce a statutory duty of candour in the NHS in Wales (a duty to be open and honest with patients or their families when things go wrong).

We fully support the overall "Putting Things Right" approach and feel it has the potential to deliver a much improved system for injured patients and the NHS. However, it would be a missed opportunity not to introduce a statutory duty of candour (which we have called "Robbie's Law" in our campaign). All of the arrangements in "Putting Things Right" and the draft regulations are based on investigating and responding to 'concerns' or 'complaints' lodged by patients, the public or staff. **The trouble is, if a patient safety incident which causes harm to a patient is not brought to anyone's attention, none of this comes into play.** Sadly, it is a fact that sometimes these incidents are not reported, and this is totally unacceptable. A duty to notify a concern would ensure everything reasonably possible is done to ensure patients and families are dealt with openly and honestly. This is entirely consistent with the rest of the reforms, which rightly guarantee support

and understanding for staff who do report incidents. Filling in this missing link would make the reform package truly patient centred and an example of best practice for the rest of the UK and Europe.

Information to patients and their families

Investigation reports must be made available to the patient concerned if the NHS in Wales wishes to achieve its aim of being open. A patient must be informed if any harm is caused unless the harm caused is insignificant. The duty to inform the patient only if 'moderate or severe harm or death' is caused [regulation 12 (7)] is insufficient. It cannot be acceptable to keep information about incidents from a patient, even if the level of avoidable harm is relatively low, if the NHS is to be truly open. NHS staff as well as the patient concerned can have greatly differing views about how significant a particular injury or loss is.

Regulation 12 (8) makes provision for the investigating body not to inform or involve the patient if the investigating body believes it would not be in the interest of the patient. We have serious reservations about this. If this regulation is needed, it should be limited to the same criteria as set out the Data Protection Act ie

- Likely to cause serious harm to mental health or condition of the individual concerned
- Likely to cause serious harm to the mental health or condition or another person

Also, we suggest that it should be made a requirement for decisions of this nature to be made independently of the investigating body because of the potential conflict of interest.

If the patient is represented under the scheme their representative should be informed of the investigation and where possible involved in it.

Regulation 28 (3) says that no copy of an investigation report needs to be provided "before an offer of redress is made" We believe this to be at odds with the stated intention about openness. The investigation report should be made available to a patient whether or not it leads to an offer of redress. To withhold such information would bring the whole scheme into disrepute.

The provisions under regulation 28 to not disclose a report where it is likely to cause the patient "significant harm of distress" should be limited in the same way as regulation 12 (8) above.

Initial advice for patients and their families during the investigatory stage

In implementing the scheme it is essential to recognise that there is still a long way to go before a fully open, transparent and thorough investigation will be carried out every time something goes wrong. A lot of progress has been made but much more needs to be done. The practical arrangements for

advice and representation need to be clearer and stronger. This will help ensure the arrangements are effectively implemented, give patients confidence and ensure credibility. Over time the need for advice and representation will be reduced as the investigatory process is refined and the commitment to always being open is achieved. The scheme must be robust; patients and their families must have confidence their concerns are being considered and interests protected.

It is within the spirit of the proposals that the patient is fully involved, appropriately advised and, if necessary, represented. If something has gone wrong with a patient's treatment and harm has been caused they should be advised as soon as possible. Problems arising out of treatment can be complex and a patient should have the opportunity to get advice at an early stage. It is important the patient affected should be able to formulate their concerns properly and that the investigation is a two way process. In general patients will need to be supported through the process in order to be involved in the process.

The support and advice needs to be specialist and independent. Discussions leading up to the draft regulations being published envisaged a combination of Community Health Council and AvMA services being commissioned. We therefore recommend that this is reflected in the regulations.

Legal Advice and representation

The regulations do not provide any detail as to how and when legal advice and representation will be made available. The fees to be paid have not been specified and it seems open to individual trusts to operate this part of the scheme in different ways.

The scheme should allow for the different scenarios set out below.

i) It is clear to the legal adviser all potential liabilities have been investigated and all heads of damage considered. Legal advice would only be needed with respect to the level of compensation.
ii) Although liability has been admitted the legal adviser needs to investigate further and in some cases will need to instruct experts (this may be the case even if the trust has already commissioned expert reports at the investigatory stage. Experts rely on the information provided and instructions given, if this information is incomplete or unclear the patient's adviser cannot be expected to advise properly with respect to compensation).
iii) Compensation has not been offered or liability admitted but the NHS body accepts that matters should be investigated further and it is appropriate to use the scheme.
iv) The scheme should be flexible enough to allow for the patient's legal adviser to be involved at the investigation stage in some cases. This would allow an expert to be jointly instructed at this stage and avoid duplication of costs at a later stage.

NHS Staffing Resources

The stated intention to have “a single integrated, multi-skilled team” to manage all concerns is key. This approach is welcome and it is essential that these teams have the resources and skills to investigate concerns thoroughly and the reporting lines within the NHS in Wales are such that lessons are learnt. If these teams aren’t effective none of the objectives set out in these arrangements will be achieved.

Primary Care

The intention to extend these proposals to primary care is welcome although there are clearly practical issues that will mean that it is likely to take longer to implement these arrangements in this setting.

Process

It is intended that the ‘Independent Review’ stage of the current complaints process is removed. AvMA believes it is essential, if this is the case, that the Ombudsman has sufficient resources to deal with matters not resolved by way of local resolution and the criteria to be used by the Ombudsman to consider cases should ensure clinical issues can be investigated if not resolved locally.

Limitation and offers of compensation

The limitation holiday should start with the date a concern is raised not (as currently set out) when the NHS considers itself liable

Under the draft regulations the limitation holiday ends 3 months from the date on which the NHS makes as an offer of financial compensation. The limitation holiday should be extended if the patient seeks advice and the solicitor dealing with this matter needs time to investigate and/or obtain expert advice.

Intention to bring legal proceedings (Regulation 14 1 (i))

The regulations currently say that if a patient says there is an intention (or presumably may be an intention) to bring legal proceedings then that person is excluded from these arrangements. This would be a retrograde step. Injured patients often say they ‘intend’ to take legal action, before they know and understand all of the information and their options. Any NHS patient should be able to benefit from the approaches set out in these proposals. It would be wrong to exclude those who think they will need to take legal action over an avoidable injury or are seeking advice prior to making a final decision about litigation. Only those patients who have commenced proceedings or who have instructed a solicitor to commence proceedings should be excluded.

Learning lessons

Consideration should be given to auditing the remedial action promised if something has gone wrong to ensure effective action has been taken. AvMA has seen good practise being achieved in this area but is also aware of many cases where mistakes are admitted, action promised but the same thing happens again.

Speedy Resolution

The 'Speedy Resolution' scheme is in place and working. Once the 'Putting Things Right' proposals are put into practice and seen to be working 'Speedy Resolution' should be absorbed into the main scheme.

Tariffs

The tariff approach is only appropriate for lower value claims. In addition care should be taken that the tariff approach does not fetter the discretion of a Trust in deciding the level of appropriate compensation or in taking into account the individual circumstances of the case.

Financial compensation

It is not clear what is envisaged under Regulation 25 which refers to pain suffering rather than general damages a term which would include pain suffering and loss of amenity.

Even if the cap of £20,000 is meant to mean pain, suffering and loss of amenity this cap would allow very large claims to be considered under the scheme as special damages can be substantial.

There are concerns that the approach outlined in these proposals may not be appropriate for larger claims because they are likely to be more complicated, and could not be properly examined by the patient's representative within the limitations of the scheme. The scheme should be restricted in its infancy until any problems have been ironed out, and the capacity to deal with higher value claims has been demonstrated. Until the scheme has become established the financial cap for the global value of financial compensation should be £25,000 with the proviso that a higher ceiling can be set if both parties agree.

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