Consultation on the Medical Innovation Bill: RCGP response

To whom it may concern,

This response has been sent after the date for the consultation formally closed. However we would ask that this response is also considered. The first draft, as sent out for consultation, did not seem to involve GPs. However, the most recent draft, published after the closure of the consultation, does involve GPs as part of the ‘multidisciplinary team’. We would therefore like the opportunity to respond and hope that an exception can be waived because of this change in the Bill’s scope.

The ethos of innovation in medicine is one which the RCGP and medicine more broadly would support. However the Bill as presented (draft 10th June 2014) creates several problems which we are concerned would have a negative impact on patients.

The Bill says, (2) “It is not negligent for a doctor to decide to depart from the existing range of accepted treatments for a condition if the decision is taken in accordance with a process which is accountable, transparent and allows full consideration of all relevant matters”. This is already the case, and there is no need for further legislation to reiterate this. Daily, in general practice, shared decisions are made with patients which depart from guidelines which do not, for whatever reason, suit that patient.

In section (3) b, the Bill states that the doctor proposing the treatment makes “consultation with appropriately qualified colleagues, including any relevant multi-disciplinary team;” . While GPs are indeed part of this team, we are already, as per the ‘put patients first’
campaign, struggling to provide core services to our patients. The responsibility involved would likely incur the need to do a systematic review on the treatment proposed, examine and address the ethical concerns, and be involved with concerns over capacity and information in consent to treatment. GPs are under resourced at present and cannot undertake this responsibility safely at this time.

In section (3) it is stated that “consideration of all matters that appear to the doctor to be reasonably necessary to be considered in order to reach a clinical judgment, including assessment and comparison of the actual or probable risks and consequences of different treatments.” This will not be possible. The point of the Bill seems to be to introduce ‘innovative’ treatments outwith trial conditions and where the outcomes are speculative or unknown. It is crucial that doctors admit uncertainty and work to try and reduce it rather than making dangerous assumptions about the effectiveness of an intervention.

In section (4) it is stated that “Nothing in this section permits a doctor to administer treatment for the purposes of research or for any purpose other than the best interests of the patient”. This is a fallacy. The purpose of the Bill seems to be to introduce treatments where there is no substantive or convincing evidence behind their use. It is therefore unknown as to whether the intervention is the best interests of the patient. Indeed, using interventions in research is to be promoted, not banned, since this is how (through the process of systematic review, ethical approval, and publication of results) we can reduce needless repetitions or useless or harmful interventions and identify useful interventions such that we can offer to others. This is the most concerning part of the Bill as we are concerned it could create unintended harms to patients both now and in the future.

We are therefore opposed to the Bill becoming law despite the good intentions behind it.

Thank you.

Yours sincerely

Professor Nigel Mathers FRCGP, Honorary Secretary of Council