Response to editors and reviewers' comments

Comment	Response
It might be helpful to describe in more detail how the ruling has changed practice on the ground. Beyond the legal cases, is there any evidence available yet on what is happening in day to day clinical practice? Is it being investigated?	We have added some material to explain this.
Editors thought that the manuscript could offer more background for readers based outside the UK, and also some context on how the situation in the UK compares with other similar countries - is this information available?	We thought that comparisons with the international situation would add a substantial amount of material and change the focus of the piece, however extensive discussions of informed consent in the international context are available elsewhere in the literature and we have added some references that explore this.
Reviewer 1: the article does not answer the question posed at the outset, namely the question about the effects of Montgomery IN PRACTICE. I read that to mean in clinical practice. This is not addressed in the paper and indeed one would imagine it would require an empirical study of some sort. That section should be changed so as not to deceive the readers!	This has been worded more clearly and additional material incorporated (see notes above)
R1: the authors occasionally dismiss objections to the Montgomery standard of consent too easily. A good example of this is at the top of p.4, where the authors address the points about the risk of confusing patients with information, leading to poorer decisions and greater time spent by doctors explaining matters to patients. The answer given refers to communication being "appropriately handled" and "good communication" but these raise the question: "how?". These 'feel good' phrases should be fleshed out otherwise they sound too facile…	This section has been rewritten to address this point.
R2: Montgomery is a not a clash between patient's autonomy and medical paternalism. It is a co-operative approach between the patient and the physician for a hassle free but healthy outcome.	We did not find any substantive disagreement with this reviewer but hope the revisions we have made express this point more clearly.

R3: I would like to encourage the authors to ask themselves what could be potential advantages for doctors, patients and the healthcare system.	This would indeed be interesting but is not the focus of this commentary.

Reviewer 4's comments were the most negative; as they deal at some length with specific legal points, AS has provided a detailed response separately to these comments, below (additional explanatory notes are given in square brackets).

I think Medical Law contributions to the BMJ should be welcomed and encouraged, insofar as there is the potential to inform and convince a significant population of the British and global community of health care professionals. However, it is vitally important that articles present an accurate picture of the law, and engage in suitably critical treatment of claims about the law (what the law is, what its implications are etc) by both healthcare professionals and others. I take it that these are necessary features for a medical law and ethics analysis article, and I have therefore proceeded along these lines. Unfortunately, this paper at present fails to satisfy these conditions, and I am not able to recommend publication. Moreover, I am slightly concerned that negative consequences would attach to its publication at present, given the misleading picture it presents of the law. My detailed comments are set out below.	As the lead on the legal side, I regret that the reviewer suggests that there are inaccuracies in the legal analysis. I note that the other legal reviewer, who is a practising barrister (as am I) does not consider that the article is inaccurate. By way of explanation, not only did I appear in the Supreme Court in Montgomery and therefore present for the duration of the case, I appear in cases of this type most of my practice. I have attended many seminars, delivered lectures, read widely on comments about it. In writing the article, as far as I contributed, it was intended to provide a non legal approach. I have no doubt that the academic world can and will debate the meaning of individual sentences, the effects, and consider each and every nuance. That, in my opinion, is not what an article in a medical journal is designed to do. The place for such debate – if there is a debate to be had – is in academic literature in the legal profession. No doubt if any doctor wishes to delve deeper in the legal questions, he or she can do so. But the purpose of the article from a legal point of view is to provide an outline in as few words as possible, about the case. I deal with particular comments below.
'to satisfy the standards of informed consent'	The purpose of the phrase is to use it as it is in common currency. There is in my opinion a

No. To meet the standard of care required to avoid, all else being equal, liability in negligence. There is no single doctrine of 'informed consent' in English Law.	single doctrine – one can argue as we did in Montgomery that consent cannot be obtained unless it is “informed” – but the concept is well understood by both lawyers and doctors. And, incidentally, we are not just talking about “English” law. The Montgomery case was Scottish. If the reviewer is suggesting that there is no single “doctrine” of informed consent in the UK, that is simply incorrect in the context of the article which everyone understands is being considered.
‘what a patient should be told depends upon what the individual patient wishes to know and not what the doctor thinks they should be told.’ This risks seriously misleading the readership of the BMJ as to the test of materiality of risk, and hence the standard of care in information disclosure cases. The passage gives the impression that the standard of care depends either on some kind of individual patient test, when in fact the combined speech of Lords Reed and Kerr in the UKSC clearly supports the prudent patient test.	It is clear from all judgments, not least Lady Hale’s, that whilst there is an element of objectivity, it also includes subjective concerns. The context of the article makes it clear that the process is one of engagement with the particular patient. As was discussed during the hearing, and understood by all including the justices, made clear in the written submissions and is clear from the judgments, the patient centred test is vital; that is the point which is sought to be made in the article. Again, if one wishes to descend into a legal academic debate, the place for that is legal academic press, not an article which is for doctors or the public, and encourages the reader to read the case which is designed to be read by the public and understood by them.
If this paper is to be published in a generalist medical journal with extensive readership, it is crucial to provide an accurate statement of the law. BMJ readers cannot be expected to go to the judgment of UKSC for their law, and thus may rely on material inaccuracies, to everyone's detriment.	Why not? The judgments are made available in a readable format. They are no longer written in a way that predated the Supreme Court which was verging on impenetrable. I reject the suggestion that it is inaccurate. The reviewer may disagree with me as to the meaning of it when attempting to summarise it. His criticism is in no way constructive, which is rather a pity.
‘some argued (in particular the General Medical Council who intervened to	I would prefer to write my own précis of the judgment, rather than adopt what is said in the “extensive academic treatment”. There is a limit

make submissions in the case) that it had simply enabled UK law to catch up with current GMC guidance; others hailed it "the most important UK judgement on informed consent for 30 years."' Given that the Montgomery judgment has been subject to extensive academic treatment, one would expect a better snapshot of the competing arguments, or at least some references. eg There are two recent papers (Brazier and Farrell, and Montgomery and Montgomery) n the BMJ's sister journal, the JME, that take adopt quite different evaluative stances on the judgment of the UKSC.	to the number of words that can be put into an article of this type, and to engage in a discussion of the competing academic arguments is not only unhelpful but not for an article for Doctors or the general public. Whilst I realise that an academic is reviewing the article, it is my own experience that the courts rarely rely upon or are interested in academia and when they are, it is to help decide cases, not to try to pick over them to consider whether they are right or wrong. What I am clear about is that doctors will be even less interested in considering a legal debate about what Montgomery means when it means what it says. [Note additionally that the papers cited had not been published when our piece was first written; the revision now incorporates these, as well as other literature which has since become available.]
'Doctors expressed' Every doctor? Or just some?	I assume that the reviewer appreciates that no one has suggested that every single doctor has expressed a view on anything. To be honest, I find that comment flippant and unhelpful. It rather betrays the approach of the reviewer who has a negative and over picky approach to the review. It is clearly intended to convey that a body of doctors expressed a view and this article was co-written by a number of doctors: I would think that they would know who was expressing that view.
'and that the retrospective application of the judgment may "open the floodgates" for claims in relation to doctors' past actions[6].' This is not at all an authoritative source for interpretation of the law. It is hard to see how the Montgomery judgment could have retroactive effect. The author misunderstands a fundamental point about the	No I don't misunderstand it. The judgments in for example in In Re Spectrum Plus in [2005]; and Deutsche Morgan Grenfell v Inland Revenue in 2007. It is impossible that the judgment has anything BUT retroactive effect. The point of the decision in the second case above is that the court could not change the law prospectively. The reviewer is simply wrong on this. Indeed, at conferences involving some of the most experienced leading counsel, this point was made without argument.

application of a change in the law brought about by UKSC decision.	
The Montgomery ruling applies to Nadine Montgomery's litigation, whose facts arose in the past, because the question of law that the judgment settles arose during that case.	I don't understand that. The point is that until Sidaway was departed from she lost; that the events occurred in 1999 when Sidaway was applicable, meant that until the law changed (or more correctly was declared to be in that way all along) she would continue to lose.
The Montgomery ruling does not apply to potentially actionable facts that occurred outside the limitation period (Limitation Act 1980, s 1 in E&W) prior to the judgment.	First, the Limitation Act does not apply in Scotland. Both in England (section 33) and Scotland (section 19A of the Prescription and Limitation (Scotland) Act 1973 as amended) contain provisions for the delay in litigating beyond the limitation period. It is also a sad fact that in many cases, the claimant or pursuer is incapax and in both jurisdictions, the time limit does not begin far less end. During minority, the clock is not running. Accordingly, there are many cases where the claims can still be brought and are of considerable vintage. If I may say so, the reviewer is not approaching this from a practical point of view, and inexperience in litigation is obvious. Day in, day out, I am dealing with cases where the event occurred decades ago. Amendments are taking place in historic cases, and often after amendment, settlement occurs. Therefore, the point made by the reviewer is wrong in law, wrong in fact, and wrong in practice.
Re floodgates. it is also important not to frontload this paper with alarmist medico-legal arguments that receive no critical scrutiny. As you point out, in line with Brazier and Farrell in the JME, the law is now aligned with what the GMC has taken to be good medical practice for a substantial period of time.	The problem is that doctors were not following GMC practice – and I don't mean every doctor, I mean the ones that I have cause to litigate against. The fact that there are guidance papers, does not generally elevate them to a statement of legal requirement.
'While this suggests that Montgomery should not demand changes to	The paper is not intended to be argumentative.

practice, it may nevertheless have an impact on doctors' behaviour and on other potential cases.' This is not an argument.	
'The application of Bolam to consent cases had been affirmed in Sidaway v Bethlam Royal Hospital Governors and others;' Another material inaccuracy. Only Lord Diplock's speech in the House of Lords unequivocally endorses Bolam. Lords Bridge, Keith, and Templeman held (roughly) that a judge might find a material risk ought to have been disclosed notwithstanding that non-disclosure had professional support.	This is an unnecessary comment. It should be saved for legal academic press. I doubt that doctors or the public would be interested or impressed with
'patient's right to make informed treatment decisions' The language of rights doesn't really feature in Sidaway. It comes much later in Chester v Afshar.	Lord Templeman refers to the "right" to information in Sidaway.
'Montgomery soundly rejected the application of Bolam to consent,' I take it here that 'soundly' refers to an endorsement of the Montgomery judgment. However, you offer no argument as to why we should accept Montgomery.	The reason is because Montgomery is a decision of the UK Supreme Court and a decision of seven justices. It is therefore the law. The purpose of the article is not to offer an argument as to why Mongomery is wrong, it is to tell people what it says. [Note also that this wording has been changed, since the reviewer's comment appears to reflect a misunderstanding of how the term 'soundly' was intended.
'"The test of materiality is whether… a reasonable person in the patient's position would be likely to	The word in the quoted paragraph of "particular" makes it, well, particular to the patient.

attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'" This is the correct test of materiality. But it is inconsistent with what you said above re individualised standard of care.	
Description, no evaluation. This is supposed to be an Analysis article. Is it true that Bolam is dead? Is it true that the test is now patient-focused? Because the Supreme Court said so.	The article, again, is not intended to be argumentative or evaluative. It is to be informative.
'does the decision in Montgomery work retrospectively, and if so might it trigger a flood of claims challenging past cases on the basis of consent?' As I tried to explain above, the Montgomery judgment does not have retroactive effect, although it will likely apply to actionable facts within the limitation period. The misunderstanding of the law seems to have started the Lanarkshire NHS Trust's medical director. Therefore, the discussion of retroactivity in this section is rather unnecessary.	That is completely and utterly incorrect as I point out above. The fact is that the courts have numerous cases before them that are in essence retroactive. It is that quality that makes this of interest to doctors I have discussed matters with at conferences, and indeed their insurers.
'It ought to be obvious, however, that in practical terms the retrospectivity of Montgomery is at least back to 1999,' This is false.	In what way? It is absolutely correct!!

‘One in Scotland has so far been unsuccessful’ Yes, but it is not clear from the judgment why.	The judgment of the court was appealed unsuccessfully. The matter is to be considered in due course by the Supreme Court if permission to appeal is allowed. [Note: information to this effect has been added to the text.]
‘others are understood to have settled before litigation ever commenced or was concluded, as the claims were unanswerable in the light of Montgomery.’ Need evidence to support this claim.	Why? Settlements are confidential, but I am aware of colleagues who have settled regularly following Montgomery. This is not held up as being a statistical analysis which requires evidence. It is an article designed to inform. Anecdote is sufficient.
‘Examining some of the cases in which Montgomery has been considered illustrates its interpretation to date.’ Given that there have been a significant number of post-Montgomery cases (Nigel Poole QC keeps a tally), the authors should provide further justification for selecting these particular cases.	I also keep a tally. It is not, again, a legal article in which every case is analysed.
It is generally better to frame things in terms of arguments, rather than what 'some' people think.	This is not an argumentative paper.
While I agree that the information overload concern is somewhat overstated, you should tackle the objection head-on, rather than saying that the concern would not arise in situations of appropriate/good communication. You need an answer for poor communication on the part of physicians too.	[This has been addressed in response to comments from other reviewers; see above]
‘Ethically and legally,	I disagree completely. I have no doubt that the

however, the position is clear: doctors may not withhold information simply because they disagree with the decision the patient is likely to make if given that information.' I think the position is ethically more controversial than you suggest, given recent influential work on paternalism eg Sarah Conly. Again, you need to provide arguments in an analysis paper.	legal and philosophical academic world would like to have a dog in the fight about whether Montgomery is right or wrong. That said, Sarah Conly's work was not referred to in the Supreme Court, either in argument nor in the judgment. The place for debate about whether philosophically Montgomery is right or wrong, should be left in the academic rooms. It is not helpful to start to argue that Montgomery is right, or wrong, or otherwise when what matters to doctors and practitioners is what the law would appear to be in practice. I hope I am forgiven for not being aware of the "influential" work of Sarah Conly. I am unclear as to who it has influenced, but it did not influence the Supreme Court justices.

Andrew Smith QC