PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Patient safety regulation in the NHS: Mapping the regulatory landscape of healthcare.
AUTHORS	Oikonomou, Eirini; Carthey, Jane; Macrae, Carl; Vincent, Charles

VERSION 1 - REVIEW

REVIEWER	Mike Durkin Centre for Health Policy Institute of Global Health Innovation and NIHR Patient Safety Translational Research Centre Imperial College London United Kingdom
REVIEW RETURNED	08-Feb-2019

GENERAL COMMENTS	This review from the Oxford Group led by Charles Vincent correctly identifies the concerns relating to the burden of regulation that may be seen to exist across the NHS in England. They have carried out an exhaustive trawl of those organisations and bodies that may be seen to have a role in regulating, advising and planning the current healthcare system in England. I believe though that given the current context there are some minor amendments and additions that would be worthwhile. The use of the term Department of health (DH) should be amended to read as Department of Health and Social Care (DHSC). this change took place in 2018 and therefore deserves to be recognised. The context within which the paper sits may be enhanced by reference to the regulatory journey that has taken place from 2002 following the Milburn "Dissolution of the Health Authorities" which replaced the disparate 100 HAs by 28 Strategic Health Authorities (SHAs). In quick succession from 28 in 2002 to 10 (quasi regions) in 2006 to be replaced by 4 (North, South, Midlands and East of England) in 2010; during this time the move from PCGs to a reduced number of PCTs should be recognised. The resulting reduction in regulatory bodies was then replaced by the Lansley Moment which brought into place the profusion effect of the CCG and the Area's within Regions under the control of the David Nicholson at the NHS Commissioning Board.

	I enjoyed the term Organisations with Regulatory Influence and in that spirit I believe the discussion should make note of the various bodies and local collectives brought into play since the emergence of the Five Year Plan during the NHS England/Simon Stevens Era with its seven models of care that tried to bring the planning and regulation of primary, secondary and social care together with local authority influence eg Multispecialty Community Providers and Primary and Acute Care Systems (https://www.kingsfund.org.uk/projects/nhs-five-year-forward-view). Since that time the "New Models of Care" being subordinated by the Sustainability and Transformation Plans (STPs) which brought into play a governed structure with Chairs, CEOs and Boards to regulate and Plan across 44 localities. !n recent times the term Integrated Care Systems (ICSs) has now further developed the taxonomy!

REVIEWER	David J Carter Senior Lecturer, Faculty of Law, Law | Health | Justice Research Centre, University of Technology Sydney. Member, Centre for Health Services Management UTS. National Health and Medical Research Council Early Career Fellow
REVIEW RETURNED	11-Feb-2019

GENERAL COMMENTS	Thank you for the opportunity to review this draft paper submitted by Oikonomou et al entitled 'Patient safety regulation in the NHS: Mapping the regulatory landscape of healthcare'. The authors present a paper that reports on a desktop mapping exercise aimed at what they term the 'regulatory landscape' for patient safety in the NHS. The authors should be congratulated on selecting a topic of significant importance for both contemporary patient quality and safety research and with potential practical benefit for both government, regulatory agencies, stakeholders and other participants in the delivery of healthcare services in the NHS. The authors define 'patient safety regulation' – the central phenomenon of interest – as directed at ensuring '…safe, reliable treatment for patients and a safe working environment for healthcare professionals' whilst providing 'potentially valuable feedback to provider organisations, supporting improvement and ensuring that high standards of performance are maintained'. Given this definition and aim, the authors rightly note the criticism of patient safety regulation regarding effectiveness, inflexibility and forms of undesirable compliance behaviours that some writers have argued it can create. Noting that there is a tradition of criticism of patient safety regulation, the authors – rightly in my view – propose that an understanding of the regulatory landscape is required prior to engaging in question of critique or reform. The method selected by the authors is appropriate for the purposes outlined by them. The results they report are clearly communicated in a step-wise manner. However, there are a number of important – and some essential – areas where the authors might revise their paper prior to publication. In particular, these relate to areas where the authors should provide more clarity as to (a) the scope and

	meaning of important concepts and assumptions that drive this research, and, perhaps most importantly, (b) where they must exercise more restraint in constructing conclusions that are supportable by the data, literature and argument presented in the paper. For the reasons outlined below, I believe that the paper should be published subject to some selected revisions and copy editing. I provide commentary below on some important areas for the authors to consider in their revision process. 1. The authors must provide a revised statement of what they mean by 'regulation' at an earlier phase of the paper. Whilst there is a statement developed at 7 of the review draft, the definition lacks any obvious connection to the wider and more developed regulatory theory literature, and suffers for it. Without a more robust definition questions arise as to why, for example, the authors constrained their inquiry to 'organisations'?; does their definition of 'organisation' include important Offices (in the sense of a public function) such as that of the Coroner?; Why are only domestic 'organisations' reviewed – what of transnational, European or global regulatory bodies? These questions are listed here merely as guidance. I do not believe the authors must answer these either in responses or revision. They are offered simply to illustrate what a more robust definition might provide the paper. Naturally, the authors might wish to argue that the existing definitions of 'regulation' offered by that literature are insufficient for their purposes. If that is the case, then this should be clearly stated with reasons provided. 2. Related to point [1] above, the authors should revise the description of regulation and regulatory activity provided in the pages leading to 7. In particular, the authors should provide a clear rationale for confining the review to NHS regulation, rather than health services regulation more broadly (that is, including private sector provision etc). Moreover, the discussion in that section seems to conceive of regulation by way of a focus upon the practices of external inspection and 'true external oversight' as the authors put it. This is particularly pronounced in the brief historical overview where the authors argue that 'broad sectors of the NHS remained free of external oversight or regulation throughout [the period until the late 1990's]'. However, this conflicts with what I read the authors' intention/view of regulation provided at 7. This is particularly true where the earlier text conflates or limits its discussion of 'regulation' to matters of 'external oversight' including inspection, and as a practice carried out by government or, alternatively, government-established regulatory bodies in this earlier part of the paper. The authors should adjust their introductory materials to make clear their broader understanding of regulation. This confusion as between the definition of regulation provided at 7 and the material given beforehand – which focuses only on external and governmental regulation - demonstrates the potential contribution that a more robust definition of regulation might perform here. Regulation, as understood by much of the regulatory theory literature takes a 'broad view', see especially authors like Julia Black et al and others who draw their lineage from the Responsive Regulation theories of Braithwaite et al. 3. Given my comments at [1] and [2], the authors must more clearly delineating the scope of their review throughout. This is largely a drafting/re-drafting exercise. It may mean that the authors choose to state their focus as being something more closely resembling a review of formal, governmental and quasi-

	governmental regulation rather than 'regulation' in its broad meaning. This is particularly important for statements like '[w]e aim to map the landscape of patient safety regulation in the NHS and understand the totality of influences on NHS Trusts.' Whilst this may be true of a broader project, this paper's important work is to make a more focused contribution. 4. The authors should revise their interpretation of the multitude of regulatory actors throughout, especially in the discussion and interpretation sections. For example, the authors write that '[t]he multitude of organisations that are simultaneously involved in various types of activities overseeing healthcare is striking'. It is true that there are a multitude of organisations that are involved. And the large number of them may well be 'striking' in some ways, and to some sector participants – perhaps especially patients. However, the broader healthcare regulatory literature already documents, in multiple contexts, the existence of such multitudinous and overlapping regulatory actors and influences on health care practice and service delivery. See in particular the work of Judith Healy (see especially, Improving health care safety and quality: reluctant regulators. Routledge, 2016.), Healy and other's work on polycentric and responsive regulatory nature of healthcare globally, the work of Alan Merry and Alexander McCall Smith on criminal and other legal influences followed by the work of Oliver Quick. 5. The authors rightly detect the important role of 'other' bodies or organisations in the regulatory mix. However, given their particular nature (i.e. as not self-consciousness 'regulatory') the authors should consider and account for the complex relationship and difficulties as between these regulatory actors roles and responsibilities as they interact with their regulatory influence. For example, what might the 'other' roles of the Royal Colleges and others play in relation to patient safety regulation? 6. The authors rightly conclude that there is both a proliferation of regulatory actors. To this, they provide a limited review of existing literature on the views and experiences of regulatees. However, given the limited and selective engagement with that literature the authors must treat any conclusions they draw from this literature with more restraint by revising their wording. For example, the authors write that some regulatees are reported to have 'found inspection processes burdensome, particularly as a result of large-scale and incoherent information requests from the overseeing agency.' However, the conclusion that seems to be drawn here is one that gestures towards the source of this reported difficulty being the proliferation of regulatory actors ('bewildering range of disparate organisations and agencies'). This is an inappropriate conclusion to draw from this data without more data or appropriate argument. Conclusions of this nature, and this is not the only one, must be revised. For one, the authors do not consider – at least within the text – that the attitude of regulatees might well not be impartial. Rather, they seem in their current drafting to uncritically accept the attitude expressed by regulatees as both normatively justified and warranted in the circumstances. It will, of course, be of little surprise to the authors that regulatees often resent the imposition of regulation, and regulatory activities upon their work. However, such resentment must be placed within the context of the interests inherent in the regulator/regulatee relationship and then tested by further research. In this particular instance, a more appropriate conclusion might be to interpret the reported lack of coordination of regulatory actors, and the reported low quality of their request processes and to raise the hypothesis/question as to whether a part

	of this reported dissatisfaction by regulatees is due to the proliferation of regulatory actors. This should be done whilst noting the source of complaint being the regulatee – all of which is perhaps a prompt for further research on the part of the authors. Other examples of similar conclusions that must be revised include but are not limited to: a. In the structured abstract, 'continual regulatory requests and visits distract and impede locally driven initiatives to improve safety and quality…': the authors do not provide sufficient evidence to support this claim of either 'continual' requests, their distraction/impeding of local activities, their less effective nature than local activites etc. b. 'However the overall impact of the totality of the regulatory system makes it impossible for regulators to act effectively and places a massive burden on NHS providers which almost certainly detracts from safety and quality improvement initiatives': the authors must revise this statement which is not sufficiently supported by the methods or evidence presented by the paper; c. '…major simplification of the current system which in turn could produce huge savings and more effective regulation': such a 'major simplification' may well produce savings. However, the authors must revise and reframe this statement so that it accords with the evidence presented in the paper. d. 'unwittingly devoted to regulation' (see [9] below for example). 7. Related to my commentary at [6] and elsewhere the authors should consider whether their approach to regulation and regulators is sufficiently critical, especially with regards to their own pre-conceptions of regulatory actors, regulatory activities and the effect on regulatees. For example, in their description of regulatory actors presenting health and hospital services with 'large-scale and incoherent information requests from the overseeing agency' that were interpreted as 'burdensome', the authors should exercise more critical distance from the claims of regulatees. Whilst regulatory actors may well impose requests that are interpreted as burdensome, this does not mean that they are not warranted nor justified. Moreover, the drafting at present seems to develop an unquestioned contrast between regulatory actors that make 'large-scale and incoherent' requests and hospital and health services who are the victim of such burdensome requests. There are no doubt improvements to be made, however, such a contrast occludes the long history of health services producing unsafe or low-quality health services, the history of intentional or reckless evasion of regulatory oversight and I think unfairly characterises regulatory actors – and not health or hospital services – as the only producer of incoherence or burdensomeness in the execution of their work. I trust the authors do not regard this as mere 'nit-picking', but rather as a provocation to push their important analysis and research further by adopting a more critical stance as to this field in both their paper and future work. 8. In the conclusory sections of the paper, the authors introduce the question of the financial cost of regulatory action. The authors must provide significant, further consideration and evidence regarding cost or significantly revise this discussion. It appears as if 'out of nowhere' at present, and is not currently supported by the data/method undertaken in the paper or their engagement with the existing literature. The paper reports on a review of regulatory

	organisations, not their cost of operating, the cost of compliance or the cost-benefit of both. An important, but subsidiary, question arises as to 'why financial costs' which likely means that a focus on cost is not suitable in this particular paper: What about other reasons for regulation – democratic control, monitoring of public expenditure and exercise of power? How can a claim be adequately supported in the context of the current paper that 'major simplification of the current system which in turn could produce huge savings and more effective regulation'? These claims are simply not supported by the paper as it stands – either by collection and mobilisation of data or attendant argument. 9. The authors conclude that parts of the NHS budget may well be 'unwittingly devoted to regulation'. This will likely be true. However, the authors should consider what they include in the scope of this claim: does it include the development, dissemination and implementation of evidence-based medicine and other standards that various of the regulatory actors they identify use to influence the 'flow of events'? What of other forms of regulatory activity that would be included in the definition of 'regulatory' or 'regulation' adopted and developed by colleagues such as Black or Braithwaite? Finally, related to my points at [7], [8] and elsewhere, the authors must consider the counter-factual: that the various bodies, their multiplicity, overlapping jurisdictions and particular practices either in whole or in part contribute to patient safety. This is the obvious counter-factual that must be considered by the authors, and attending to the possibility that some or all of the regulatory actors and practices they map might in fact make a contribution will work to temper some of the conclusions they draw in this draft and I hope provide a suitable foil to the adoption of an uncritical perspective on regulation in this field. It might well be that none or many of the regulatory actors and their practices in fact contribute positively to patient safety. Alternatively, it might be that the contribution currently made by a conglomeration of many actors might be made as well or more efficiently (economically or otherwise) by fewer actors. However, at present, the paper as drafted presents evidence as to the regulatory landscape, supported by a selected and brief consideration of some existing literature. Subject to my comments it performs this task well, and for that reason should be published following revisions. However, the paper does not report nor engage with data or sufficient argument regarding the financial cost of regulation (including attendant cost-benefit analysis), nor an evaluation of regulatory practice, nor a critical review of regulatory systems design. That is, whilst it makes a series of claims regarding regulation, at present the drafting simply claims them without directly mounting an argument or providing justification for such claims contrary to the counter-factual raised above. Rather, it engages in an important critical, interpretative mapping of regulatory organisations and their mechanisms of influence on the NHS. Until and unless the paper or further research engages with the broader/other aspects of the regulation of patient safety, the authors should continue to draw appropriately circumspect conclusions and recommendations based on the evidence they have amassed. This is not to say that the authors should not argue for regulatory reform – even radical reform. They are well placed to do

	so and I hope that the programme of further research that they gesture towards develops the much needed evidence for constructing and assessing such proposals.

VERSION 1 – AUTHOR RESPONSE

Mapping the regulatory landscape of the NHS	
Reviewers' Comments	Revisions Summary/Notes/Actions
Reviewer 1	
This review from the Oxford Group led by Charles Vincent correctly identifies the concerns relating to the burden of regulation that may be seen to exist across the NHS in England. They have carried out an exhaustive trawl of those organisations and bodies that may be seen to have a role in regulating, advising and planning the current healthcare system in England.	Thank you. The process was indeed exhaustive and indeed exhausting but it also gave us an insight into how difficult it is for anyone or any organisation to fully understand this landscape
The use of the term Department of health (DH) should be amended to read as Department of Health and Social Care (DHSC). this change took place in 2018 and therefore deserves to be recognised.	We replaced the 'Department of Health' with 'Department of Health and Social Care (DHSC)' in the 'results' section where we describe the DH's overseeing bodies (page 10).

The context within which the paper sits may be enhanced by reference to the regulatory journey that has taken place from 2002 following the Milburn "Dissolution of the Health Authorities" which replaced the disparate 100 HAs by 28 Strategic Health Authorities (SHAs). In quick succession from 28 in 2002 to 10 (quasi regions) in 2006 to be replaced by 4 (North, South, Midlands and East of England) in 2010; during this time the move from PCGs to a reduced number of PCTs should be recognised. The resulting reduction in regulatory bodies was then replaced by the Lansley Moment which brought into place the profusion effect of the CCG and the Area's within Regions under the control of the David Nicholson at the NHS Commissioning Board.	Thank you for these helpful suggestions. We have added two paragraphs to show that the evolution of regulation in the NHS, which we had described, needs to be seen in the context of these wider organisational and structural changes. We also include the more recent developments stemming from the 5 year Forward View. In addition, in the Results we have now incorporated the 10 Integrated Care Systems into the section on Commissioning Organisations. Section added in Introduction The evolution of the approach to regulation has been in the context of continual widespread reform and restructuring of the wider NHS. In 2002, the National Health

I enjoyed the term Organisations with Regulatory Influence and in that spirit I believe the discussion should make note of the various bodies and local collectives brought into play since the emergence of the Five Year Plan during the NHS England/Simon Stevens Era with its seven models of care that tried to bring the planning and regulation of primary, secondary and social care together with local authority influence eg Multispecialty Community Providers and Primary and Acute Care Systems (https://www.kingsfund.org.uk/projects/nhs-five-year-forwardview). Since that time the "New Models of Care" being subordinated by the Sustainability and Transformation Plans (STPs) which brought into play a governed structure with Chairs, CEOs and Boards to regulate and Plan across 44 localities. !n recent times the term Integrated Care Systems (ICSs) has now further developed the taxonomy!	Service Reform and Health Care Professionals Act merged 95 health authorities into 28 strategic health authorities (SHAs). In 2006, the number of SHAs reduced to 10 and later transformed into four clusters (North, South, Midlands and East of England) before finally been abolished in April 2013 (Turner &Powell 2002). During this time, health services commissioning was undertaken by 481 Primary Care Groups (PCGs), later replaced by a reduced number (152) of Primary Care Trusts (PCTs) in 2002, solely responsible for all NHS commissioning (Policy Navigator n.d.). Finally, under the Health and Social Care Act in 2012, PCTs were replaced by statutory, commissioning "consortia", the Clinical Commissioning Groups (CCGs). The 5 Year Forward review (Ref) tried to bring the planning and regulation of primary, secondary and social care together with local authority influence under seven models of care each covering a core set of related services (for instance, urgent and emergency care networks). Local leaders have been asked to come together into 44 areas, identified as geographical 'footprints', and draw up sustainability and transformation plans (STPs) to outline how they intend to transform services in their local areas within the funding available to them. Ten Integrated care systems (ICSs) have evolved from STPs responsible for planning and commissioning care for their populations.
Reviewer 2	
The authors present a paper that reports on a desktop mapping exercise aimed at what they term the 'regulatory landscape' for patient safety in the NHS. The authors should be congratulated on selecting a topic of significant importance for both contemporary patient quality and safety research and with potential practical benefit for both government, regulatory agencies, stakeholders and other participants in the delivery of healthcare services in the NHS.	Thank you for appreciating the work to map the regulatory landscape and the potential benefits stemming from the mapping for developing and improving regulation in various practical ways.

The authors define 'patient safety regulation' – the central phenomenon of interest – as directed at ensuring '…safe, reliable treatment for patients and a safe working environment for healthcare professionals' whilst providing 'potentially valuable feedback to provider organisations, supporting improvement and ensuring that high standards of performance are maintained'. Given this definition and aim, the authors rightly note the criticism of patient safety regulation regarding effectiveness, inflexibility and forms of undesirable compliance behaviours that some writers have argued it can create. Noting that there is a tradition of criticism of patient safety regulation, the authors – rightly in my view – propose that an understanding of the regulatory landscape is required prior to engaging in question of critique or reform. The method selected by the authors is appropriate for the purposes outlined by them. The results they report are clearly communicated in a step-wise manner.	We again appreciate the comments on the purpose and value of the study. We have also taken note of your comments below about potentially unwarranted criticism of regulation. At various points we have adjusted the text to give a more balanced approach to the benefits and costs of regulation.
There are a number of important – and some essential – areas where the authors might revise their paper prior to publication. In particular, these relate to areas where the authors should provide more clarity as to (a) the scope and meaning of important concepts and assumptions that drive this research, and, perhaps most importantly, (b) where they must exercise more restraint in constructing conclusions that are supportable by the data, literature and argument presented in the paper.	Thank you for drawing our attention to these issues. We had previously reviewed the theoretical background and were indeed influenced by these wider formulations in our approach to the study. However, we had been unsure whether to add such material into the paper. Very happy to do so (see below). We also appreciate that we should be more careful in our interpretation of the findings and their implications and have made various adjustments (see below).

1. The authors must provide a revised statement of what they mean by 'regulation' at an earlier phase of the paper. Whilst there is a statement developed at 7 of the review draft, the definition lacks any obvious connection to the wider and more developed regulatory theory literature, and suffers for it. Without a more robust definition questions arise as to why, for example, the authors constrained their inquiry to 'organisations'?; does their definition of 'organisation' include important Offices (in the sense of a public function) such as that of the Coroner?; Why are only domestic 'organisations' reviewed – what of transnational, European or global regulatory bodies? These questions are listed here merely as guidance. I do not believe the authors must answer these either in responses or revision. They are offered simply to illustrate what a more robust definition might provide the paper. Naturally, the authors might wish to argue that the existing definitions of 'regulation' offered by	As noted above we were indeed influenced by regulatory theory and have now added a section (see below) which we hope has provided a clearer rationale for the how we interpreted the organisations we should review. We agree it would also be possible to look more widely (European etc) but this was simply beyond the scope of this study – which was a mammoth exercise in itself.

that literature are insufficient for their purposes. If that is the case, then this should be clearly stated with reasons provided.	

2. Related to point [1] above, the authors should revise the description of regulation and regulatory activity provided in the pages leading to 7. In particular, the authors should provide a clear rationale for confining the review to NHS regulation, rather than health services regulation more broadly (that is, including private sector provision etc). Moreover, the discussion in that section seems to conceive of regulation by way of a focus upon the practices of external inspection and 'true external oversight' as the authors put it. This is particularly pronounced in the brief historical overview where the authors argue that 'broad sectors of the NHS remained free of external oversight or regulation throughout [the period until the late 1990's]'. However, this conflicts with what I read the authors' intention/view of regulation provided at 7. This is particularly true where the earlier text conflates or limits its discussion of 'regulation' to matters of 'external oversight' including inspection, and as a practice carried out by government or, alternatively, government-established regulatory bodies in this earlier part of the paper. The authors should adjust their introductory materials to make clear their broader understanding of regulation. This confusion as between the definition of regulation provided at 7 and the material given beforehand – which focuses only on external and governmental regulation - demonstrates the potential contribution that a more robust definition of regulation might perform here. Regulation, as understood by much of the regulatory theory literature takes a 'broad view', see especially authors like Julia Black et al and others who draw their lineage from the Responsive Regulation theories of Braithwaite et al.	Thank you. We believe that setting out the theoretical background has been very helpful in framing the inquiry and providing the rationale. We decided to add an additional section in the Introduction and have also reframed the first two paragraphs to reflect this broader viewpoint. Added text Regulation, regulators and patient safety The term "regulation" can be viewed negatively and narrowly by those who are subject to regulatory oversight (Braithwaite 2006). This seems particularly the case in many healthcare settings, where 'regulation' can often refer to intrusive and inefficient interference by external authorities that distracts from the important tasks of clinical care (Macrae 2013), and can also be interpreted as a narrow set of formal activities conducted by government agencies or other statutory bodies. However, activities of regulation are typically both much broader and more constructive than this (Braithwaite 2011; Macrae 2010). Regulation represents a wide range of different activities that seek to shape motives and attitudes within organisations, as much as policies and protocols (Shearing 1993). In healthcare, regulatory activities can encompass everything from formal regulatory inspections, to attempts to promulgate voluntary models of good practice, to efforts to support and initiate culture improvement (Mello et al 2005; Healy 2011). Moreover, regulatory activities are commonly engaged in by a diverse range of different actors and institutions across healthcare, from statutory regulators to national agencies to professional bodies to charitable organisations. The regulatory landscape of healthcare can therefore be complex. To begin mapping the current regulatory system around patient safety it is necessary to more tightly define patient safety regulation. Here, we define patient safety regulation as the processes engaged in by institutional actors that seek to shape, monitor, control or modify activities within healthcare organisations in order to reduce the risk of patients being harmed during their care. This definition aims to focus attention on the specific activities that are engaged in by 'external' actors to influence 'internal' processes of patient safety in healthcare organisations. It also aims to encompass the breadth of diverse institutional actors that engage in these

	processes of regulation, even when some of those actors may not define themselves as formal 'regulators'.

3. Given my comments at [1] and [2], the authors must more clearly delineating the scope of their review throughout. This is largely a drafting/re-drafting exercise. It may mean that the authors choose to state their focus as being something more closely resembling a review of formal, governmental and quasigovernmental regulation rather than 'regulation' in its broad meaning. This is particularly important for statements like '[w]e aim to map the landscape of patient safety regulation in the NHS and understand the totality of influences on NHS Trusts.' Whilst this may be true of a broader project, this paper's important work is to make a more focused contribution.	Thank you. We have provided a definition of regulation in the new introductory section which we think more correctly accords with the approach taken in the study and we have adjusted the text to make it clear that we are not examining the 'totality' of influences but are carrying out a more focussed review
4. The authors should revise their interpretation of the multitude of regulatory actors throughout, especially in the discussion and interpretation sections. For example, the authors write that '[t]he multitude of organisations that are simultaneously involved in various types of activities overseeing healthcare is striking'. It is true that there are a multitude of organisations that are involved. And the large number of them may well be 'striking' in some ways, and to some sector participants – perhaps especially patients. However, the broader healthcare regulatory literature already documents, in multiple contexts, the existence of such multitudinous and overlapping regulatory actors and influences on health care practice and service delivery. See in particular the work of Judith Healy (see especially, Improving health care safety and quality: reluctant regulators. Routledge, 2016.), Healy and other's work on polycentric and responsive regulatory nature of healthcare globally, the work of Alan Merry and Alexander McCall Smith on criminal and other legal influences followed by the work of Oliver Quick.	We have redrafted and simplified the entire discussion. We have made it clear that leading regulatory authors have previously commented on the existence of a multitude of organisations, overlapping activity and so on. We have clarified that our particular contribution is to actually document the full landscape (as best we could) and provide a more solid empirical base both for the observations of other authors and for future actions.
5. The authors rightly detect the important role of 'other' bodies or organisations in the regulatory mix. However, given their particular nature (i.e. as not self-consciousness 'regulatory') the authors should consider and account for the complex relationship and difficulties as between these regulatory actors roles and responsibilities as they interact with their regulatory influence. For	We agree that this is an important issue but feel it is beyond the scope of the paper and beyond the scope of our study. We do not feel the findings of our study really shed direct light on this issue and so any comments we might add would really just be speculation.

example, what might the 'other' roles of the Royal Colleges and others play in relation to patient safety regulation?	

6. The authors rightly conclude that there is both a proliferation of regulatory actors. To this, they provide a limited review of existing literature on the views and experiences of regulatees. However, given the limited and selective engagement with that literature the authors must treat any conclusions they draw from this literature with more restraint by revising their wording. For example, the authors write that some regulatees are reported to have 'found inspection processes burdensome, particularly as a result of large-scale and incoherent information requests from the overseeing agency.' However, the conclusion that seems to be drawn here is one that gestures towards the source of this reported difficulty being the proliferation of regulatory actors ('bewildering range of disparate organisations and agencies'). This is an inappropriate conclusion to draw from this data without more data or appropriate argument. Conclusions of this nature, and this is not the only one, must be revised. For one, the authors do not consider – at least within the text – that the attitude of regulatees might well not be impartial. Rather, they seem in their current drafting to uncritically accept the attitude expressed by regulatees as both normatively justified and warranted in the circumstances. It will, of course, be of little surprise to the authors that regulatees often resent the imposition of regulation, and regulatory activities upon their work. However, such resentment must be placed within the context of the interests inherent in the regulator/regulatee relationship and then tested by further research. In this particular instance, a more appropriate conclusion might be to interpret the reported lack of coordination of regulatory actors, and the reported low quality of their request processes and to raise the hypothesis/question as to whether a part of this reported dissatisfaction by regulatees is due to the proliferation of regulatory actors. This should be done whilst noting the source of complaint	1. Thank you. We agree that at various points 2. we have gone beyond the findings of the study 3. in our interpretation. We have revised and 4. simplified the discussion considerably and 5. tried to make it clear that our own findings 6. primarily concern identifying the full range of actors. Clearly this has implications for how one approaches assessing both benefits and costs of regulation, but we have framed these observations in a more neutral manner. The following phrases have, for example, been edited out (numbered as mentioned in Reviewer 2's comments): 'bewildering range of disparate organisations and agencies' A. Abstract: 'continual regulatory requests and visits distract and impede locally driven initiatives to improve safety and quality…' B. 'continual' requests, their distraction/impeding of local activities, their less effective nature than local activites etc. 'However the overall impact of the totality of the regulatory system makes it impossible for regulators to act effectively and places a massive burden on NHS providers which almost certainly detracts from safety and quality improvement initiatives' C. '…major simplification of the current system which in turn could produce huge savings and more effective regulation' D. 'unwittingly devoted to regulation'

being the regulatee – all of which is perhaps a prompt for further research on the part of the authors. Other examples of similar conclusions that must be revised include but are not limited to: a. In the structured abstract, 'continual regulatory requests and visits distract and impede locally driven initiatives to improve safety and quality…': the authors do not provide sufficient evidence to support this claim of either 'continual' requests,	

their distraction/impeding of local activities, their less effective nature than local activites etc. b. 'However the overall impact of the totality of the regulatory system makes it impossible for regulators to act effectively and places a massive burden on NHS providers which almost certainly detracts from safety and quality improvement initiatives': the authors must revise this statement which is not sufficiently supported by the methods or evidence presented by the paper; c. '…major simplification of the current system which in turn could produce huge savings and more effective regulation': such a 'major simplification' may well produce savings. However, the authors must revise and reframe this statement so that it accords with the evidence presented in the paper. d. 'unwittingly devoted to regulation' (see [9] below for example).	

7. Related to my commentary at [6] and elsewhere the authors should consider whether their approach to regulation and regulators is sufficiently critical, especially with regards to their own pre-conceptions of regulatory actors, regulatory activities and the effect on regulatees. For example, in their description of regulatory actors presenting health and hospital services with 'large-scale and incoherent information requests from the overseeing agency' that were interpreted as 'burdensome', the authors should exercise more critical distance from the claims of regulatees. Whilst regulatory actors may well impose requests that are interpreted as burdensome, this does not mean that they are	As noted above, we have now adopted a more neutral tone throughout the paper. We certainly do not intend to 'attack' either regulators or regulation. Our concern is with how regulation can be maximally effective and productive. We have made a variety of changes but in particular we have reorganised the whole paragraph at page 19 and eventually deleted these phrases (numbered as mentioned in Reviewer 2's comments): 1. 'large-scale and incoherent information requests from the overseeing agency' that were interpreted as 'burdensome' 2. 'large-scale and incoherent'

not warranted nor justified. Moreover, the drafting at present seems to develop an unquestioned contrast between regulatory actors that make 'large-scale and incoherent' requests and hospital and health services who are the victim of such burdensome requests. There are no doubt improvements to be made, however, such a contrast occludes the long history of health services producing unsafe or low-quality health services, the history of intentional or reckless evasion of regulatory oversight and I think unfairly characterises regulatory actors – and not health or hospital services – as the only producer of incoherence or burdensomeness in the execution of their work. I trust the authors do not regard this as mere 'nit-picking', but rather as a provocation to push their important analysis and research further by adopting a more critical stance as to this field in both their paper and future work.	requests I think unfairly characterises regulatory actors – and not health or hospital services – as the only producer of incoherence or burdensomeness in the execution of their work.

8. In the conclusory sections of the paper, the authors introduce the question of the financial cost of regulatory action. The authors must provide significant, further consideration and evidence regarding cost or significantly revise this discussion. It appears as if 'out of nowhere' at present, and is not currently supported by the data/method undertaken in the paper or their engagement with the existing literature. The paper reports on a review of regulatory organisations, not their cost of operating, the cost of compliance or the cost-benefit of both. An important, but subsidiary, question arises as to 'why financial costs' which likely means that a focus on cost is not suitable in this particular paper: What about other reasons for regulation – democratic control, monitoring of public expenditure and exercise of power? How can a claim be adequately supported in the context of the current paper that 'major simplification of the current system which in turn could produce huge savings and more effective regulation'? These claims are simply not supported by the paper as it stands – either by collection and mobilisation of data or attendant argument.	We agree that we went beyond the interpretation of the findings of the paper and that these issues were perhaps beyond the scope of the present paper. We have simplified the discussion and in particular removed the section on future research and much of the material on financial costs. Instead we have argued for the importance of our findings in any future examination of costs and benefits and the fact that the mapping provides the foundation for a much more stringent and detailed assessment.

9. The authors conclude that parts of the NHS budget may well be 'unwittingly devoted to regulation'. This will likely be true. However, the authors should consider what they include in the scope of this claim: does it include the development, dissemination and implementation of evidence-based medicine and other standards that various of the regulatory actors they identify use to influence the 'flow of events'? What of other forms of regulatory activity that would be included in the definition of 'regulatory' or 'regulation' adopted and developed by colleagues such as Black or Braithwaite?	As above, we agree that this goes beyond the scope of the present paper and have removed these arguments.
10. Finally, related to my points at [7], [8] and elsewhere, the authors must consider the counter-factual: that the various bodies, their multiplicity, overlapping jurisdictions and particular practices either in whole or in part contribute to patient safety. This is the obvious counter-factual that must be considered by the authors, and attending to the possibility that some or all of the regulatory actors and practices they map might in fact make a contribution will work to temper some of the conclusions they draw in this draft and I hope provide a suitable foil to the adoption of an uncritical perspective on regulation in this field.	We agree that the previous paper appeared to be a little too much 'on the side' of the organisations which are regulated which was not really our intention. We believe the current situation is equally problematic for both regulatory organisations and those regulated. In general, we believe the whole paper is now more balanced in the sense of being more appreciative of the different perspectives of all organisations involved in regulation.

It might well be that none or many of the regulatory actors and their practices in fact contribute positively to patient safety. Alternatively, it might be that the contribution currently made by a conglomeration of many actors might be made as well or more efficiently (economically or otherwise) by fewer actors. However, at present, the paper as drafted presents evidence as to the regulatory landscape, supported by a selected and brief consideration of some existing literature. Subject to my comments it performs this task well, and for that reason should be published following revisions. However, the paper does not report nor engage with data or sufficient argument regarding the financial cost of regulation (including attendant cost-benefit analysis), nor an evaluation of regulatory practice, nor a critical review of regulatory systems design. That is, whilst it makes a series of claims regarding regulation, at present the drafting simply claims them without directly mounting an argument or providing justification for such claims contrary to the counterfactual raised above. Rather, it engages in an important critical,	

interpretative mapping of regulatory organisations and their mechanisms of influence on the NHS. Until and unless the paper or further research engages with the broader/other aspects of the regulation of patient safety, the authors should continue to draw appropriately circumspect conclusions and recommendations based on the evidence they have amassed. This is not to say that the authors should not argue for regulatory reform – even radical reform. They are well placed to do so and I hope that the programme of further research that they gesture towards develops the much needed evidence for constructing and assessing such proposals.	

VERSION 2 – REVIEW

REVIEWER	David J Carter Law, Health Justice Research Centre, Faculty of Law University of Technology Sydney. Centre for Health Economics Research and Evaluation, Faculty of Business, University of Technology Sydney
REVIEW RETURNED	25-Apr-2019

GENERAL COMMENTS	Thank you for the opportunity to review this paper submitted by Oikonomou et al entitled 'Patient safety regulation in the NHS: Mapping the regulatory landscape of healthcare'. This is the second review that I have provided in relation to this paper, and I will take it that my earlier comments are available to the editors and readers. I have appended them here for reference. I am pleased to be able to provide this second review following submission of a revised manuscript. As I have canvassed the overarching aim and contribution of the paper in my earlier review, I will only refer briefly to those more general comments. As before, the paper reports on a desktop mapping of the 'regulatory landscape' of patient safety in the NHS. I reiterate my earlier comment that the authors should be congratulated on selecting a topic of significant importance for both contemporary patient quality and safety research and with potential practical benefit for both government, regulatory agencies, stakeholders and other participants in the delivery of healthcare services in the NHS. This is a topic that is worthy of significant attention, and that will be of interest to a number of readers of the BMJOpen as well as stakeholders in the delivery of health services. In my earlier review, I provided a set of comments and some recommendations to the authors. Most important amongst them were that, in my view, the authors must: 1. provide a revised statement of what they mean by 'regulation' at an earlier phase of the paper; 2. more clearly delineating the scope of their review throughout (a recommendation I felt was largely a drafting/re-drafting exercise); 3. treat any conclusions they draw from this literature with more restraint by revising their wording, given - inter alia - the limited review of existing literature on the views and experiences of regulates; 4. provide significant, further consideration and evidence regarding cost or significantly revise this discussion; 5. consider the counter-factual: that the various bodies, their multiplicity, overlapping jurisdictions and particular practices either in whole or in part contribute to patient safety. In addition to these five high priority areas that I identified, I made a number of comments and raised a number of queries. These were offered in the spirit of intellectual engagement with the paper and the fine work of the authors. The authors have engaged with these recommendations in a range of ways, the result of which presents a paper that I believe should be published without further revision.