BMJ - Decision on Manuscript ID BMJ.2018.044852 **Body:** 03-Jul-2018

Dear Mrs. Coster

BMJ.2018.044852 entitled "The Medical Examiner and patient safety"

Thank you for sending us this paper and giving us the chance to consider your work.

We sent it out for external peer review and discussed it at the Analysis manuscript committee meeting (present: Cat Chatfield, Paul Simpson, Prashant Jha, Emma Rourke, Robert Redelmeier).

Unfortunately we do not consider it suitable for publication in its present form. However, editors thought that your paper covered an interesting and engaging topic and would like to work towards publication. If you are able to amend it in the light of our and/or reviewers' comments, we would be happy to consider it again. The comments here are intended to strengthen your manuscript, develop the ideas presented, and allow greater depth to the discussion. The reviewers' comments are at the end of this letter - in this case they are very brief.

Editors' Comments:

- In general we found it to be timely and well-written. Could you briefly mention the topical angle of this piece now Jeremy Hunt has made his announcement? Bringing in the topicality would work well your argument would then be that this is a great idea and this is what we know about how to do it from our experience / research.
- It is more of an explainer than an analysis. Could you include a little more about the disadvantages/pitfalls of this approach or discuss some barriers to implementing it in practice? What are you trying to say apart from describing what is happening?
- Our editors are not all clinical or UK based and they noted that the paper is confusing unless you know something about how the system works already. There's a lot of assumed knowledge here that you could resolve quite easily by giving some brief explanation about the current system.
- Put the unpublished data in as an appendix enough information to understand the headline numbers e.g. a table so readers know all the denominators and a little bit of text about how/where it was collected. This is better practice than referring to unpublished data but not including the data for readers to see.
- This is very focused on secondary care. How are these roles going to impact on primary care? If they won't, then what is the implication for deaths/patient safety in primary care? A brief consideration of this would be helpful.

We hope that you will be willing to revise your manuscript and submit it within 4-6 weeks. When submitting your revised manuscript please provide a point by point response to our comments and those of any reviewers. We also ask that you keep the revised manuscript within the word count of 1800-2000 words.

Please note that resubmitting your manuscript does not guarantee eventual acceptance, and that your resubmission may be sent again for review.

Once you have revised your manuscript, go to https://mc.manuscriptcentral.com/bmj and login to your Author Center. Click on "Manuscripts with Decisions," and then click on "Create a Resubmission" located

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If accepted, your article will be published online at bmj.com, the canonical form of the journal. Please note that only a proportion of accepted analysis articles will also be published in print.

I hope you will find the comments useful. Please don't hesitate to contact me if you wish to discuss this further.

Yours sincerely

Cat Chatfield cchatfield@bmj.com

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Reviewer(s)' Comments to Author:		
Reviewer: 1		
Recommendation:		
Comments:		

Review by Tom Luce of BMJ Analysis Article by Fletcher, Coster & Goodacre submitted to the BMJ on 1 May 2018

The article (which reached me by email on 28 May) is timely and important. It reports pilot work for a new system of death certification monitoring the Government has for years been planning for in England & Wales and has said will be implemented in 2019. It addresses interesting issues about the relationship between the proposed independent statutory monitoring of death certification and internal health service reviews of patient safety and death preventability.

Its authors are well qualified to address the issues. It is properly referenced. Subject to a few small points of detail (as follows) it is convincingly supported.

Page 2, line 17: "United Kingdom" should be "England & Wales". The Medical Examiner scheme has been worked up only for E & W. Scotland has a different one. Northern Ireland has not yet decided what, if anything, to do. In page 3 line 33, the reference should be "in E & W" not "across the UK".

Page 2, lines 31-33. There is some complexity in the provenance and evolution of the "Medical Examiner" scheme but its attribution to a Shipman Inquiry recommendation is misleading. The Inquiry recommended a different scheme, involving notification of all deaths to the coroner where they would initially be scrutinised by lay staff under medical supervision. The ME scheme had originated in work done by the Department of Health soon after Shipman's conviction and was included for assessment in the terms of reference of the Home Office "Fundamental Review of Death Certification and Investigation" which I chaired and which reported in 2003 a handful of months before the relevant Shipman Inquiry report. The Fundamental Review broadly endorsed and recommended the scheme though suggested a different title. The Shipman Inquiry was critical of the scheme. Since then the scheme has evolved in two significant respects - Medical Examiners would be contracted to local authorities not the NHS and so be more independent, and would be required to consult bereaved families. These changes bring it closer to the Shipman Inquiry proposal. It would be appropriate to say the scheme in its present form "responds to the Shipman Inquiry's analysis of defects in the present arrangements" but not that the Inquiry recommended the scheme.

Page 3, lines 45-50. The referenced ONS study actually found that 12% of deaths needed change to the ICD classification and a further 10% were less fundamentally wrong. Would it be worth reporting this distinction?

Page 5, lines 15-20. The proportion of deaths identified in the referenced personal communication that should have been notified to the coroner (153/2668) is 5.7%. The proportion of deaths found to be uncompliant with coroner referral principles in the published study at reference 7 was 8%.

On page 6, lines14-21, the issue of the proposed E & W combination of ME and internal hospital reviews is suggested to have the potential of making the mortality review system "the best in the world". This implies that there are no similarly robust and searching schemes elsewhere. This may very well be right but if there were any published literature with international comparisons of death monitoring systems to support the point it would be worth referencing. I am not aware of any myself. A more general point is that the article implies – correctly, I believe – that the pilot projects – and hence the article's evidence base – is confined to E & W hospital deaths. Would it be worth making explicit that the ME scheme is intended also to cover all deaths, whether or not in hospital?

The article is intended for publication in a Journal with wide Anglophone circulation. Would be it sensible to make clear that the "Medical Examiners" proposed for England & Wales are very different in function from North American Medical Examiners? The latter run forensic pathology services for cases referred to them and, generally speaking, do not have the role of monitoring the death certification scheme envisaged for E & W MEs.

I am happy for the BMJ to communicate these points to the authors under my name.

Tom Luce, 29 May 2018. Additional Questions: Please enter your name: Tom Luce Job Title: x Institution: x Reimbursement for attending a symposium?: A fee for speaking?: A fee for organising education?: Funds for research?: Funds for a member of staff?: Fees for consulting?: Have you in the past five years been employed by an organisation that may in any way gain or lose financially from the publication of this paper?: Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this paper?: If you have any competing interests (please see BMJ policy) please declare them here: Reviewer: 2 Recommendation: Comments: A concise and accurate review of the emerging interface between the Medical Examiner function and the developing system of case note review in England and Wales together with the benefits of this alignment particularly in the light of the recent announcement on the progress of the ME system. Additional Questions: Please enter your name: Jason Shannon Job Title: Consultant Institution: Cwm Taf University Health Board Reimbursement for attending a symposium?: No A fee for speaking?: No

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