PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Maternal death audit in Rwanda 2009-2013: a nationwide facility-based retrospective cohort study
AUTHORS	Sayinzoga, Felix; Bijlmakers, Leon; Van Dillen, Jeroen; Mivumbi, Victor; Ngabo, Fidèle; Van der Velden, Koos

VERSION 1 - REVIEW

REVIEWER	Sarah Neal Southampton University
REVIEW RETURNED	01-Oct-2015

GENERAL COMMENTS	This is an interesting paper examining a relatively large number of maternal deaths. I think the purpose of the paper needs clarifying somewhat: is it aiming to provide a profile of the characteristics of maternal deaths in Rwanda: at the moment it just describes the findings, without analysing whether these are representative for all deaths within the country. Otherwise it is generally clear and the findings well presented. Introduction The introduction needs a section on the benefits of MDA, and experiences within other contexts. There also needs to be more contextual information about maternal health care in Rwanda, and how this has changed in the five years covered by the study. Methods More details are needed on the maternal death audits, and in particular how cause of deaths was ascertained and assigned. Was ICD 10 classification used? Was cause of death taken from patient's notes, and if so what level or cadre of health care provider provided the diagnosis? Was it discussed and in appropriate modified during the committee meeting? Findings The section on substandard factors associated with the deaths is rather disappointing. The category "poor case management" is very broad – can it not be broken down more? It would be interesting to try and bring out a few of key concerns and link them with recommendations: at the moment they are placed in separate tables and you cannot see how one leads to another. Alternatively maybe a joint table could be produced with both factors and recommendations linked? Were there some "headline messages" that could be taken from this? Discussion There needs to be much more discussion on the possible limitations of your study (and the methods used to gather the data). Presumably diagnosis relies on HCP diagnosis – this may be flawed due to poor diagnostic ability or limited opportunity in cases where death occurs very soon after admission. Induced abortion may be under-reported due to failure of patients and their families to provide relevant information. Changes over time may not just reflect real trends, but may reflect increased awareness of particular conditions

	due to training etc. You recognise that your study excludes deaths occurring in the community, but you don't outline how this will potentially bias your results. It will potentially mean that estimates around cause of death, avoidable health system / community factors will be not reflect the full national situation and this should be discussed. I think the findings need to be discussed within the context of health systems changes in Rwanda during this time.

REVIEWER	Olaa Mohamed-Ahmed National Perinatal Epidemiology Unit, University of Oxford, United Kingdom
REVIEW RETURNED	20-Oct-2015

GENERAL COMMENTS	Thank you for this interesting and informative article on maternal death reviews in Rwanda. This is an important piece of work, in an area where few articles reflect the experience in low-income settings. As a country which has shown great success in work towards achieving the Millennium Development Goals, it is important that lessons learnt and interventions implemented are shared and disseminated. The authors experiences and results from implementing maternal death audits will be valuable for other countries looking to reduce maternal mortality. I suggest this manuscript is accepted for publication with consideration of the following suggestions and comments. Methods 1. The strength of the methods used and the interpretation of trends will depend heavily on the processes used to define and identify maternal deaths. In particular, it is worth referring to the processes (if any) used to identify deaths outside of the maternity units. You refer to this briefly being the case after 2011 (p4, line 51-52) but it would be useful to know how this was done. This will affect the number of deaths reported during early pregnancy and beyond the puerperium, or due to indirect causes, which are often missed. 2. Does the health management information system and/or the maternal death audit programme cover private facilities or facilities run by NGOs, faith-based organisations etc? Please comment on this is the methods section. 3. Similarly, with regards to the cause of death, it is worth clarifying the processes used to arrive at the cause of death (e.g. consensus, expert opinion, case definitions, post mortem) or to acknowledge if this was determined at the local level. 4. There is no mention of research ethics, or whether confidentiality was maintained for patients and/or clinicians involved during the review process Results and Discussion 5. If possible, it would be useful to comment on the characteristics of

	cases that were not identified through MDA but were reported through HMIS. Do you know how they differ from the cases that were audited? 6. You state that only 4.6% of women identified in the MDA delivered at home, which may be misconstrued as encouraging home births. Please clarify in results (page 6, line 12) and discussion (page 9, line 39) that this only refers to women who delivered at home and died in a facility. The proportion of women who deliver at home and die at home has not been enumerated, and cannot be commented on. 7. As you righty comment (page 9, lines 8 -14), the fact that the facility-based MMR (69.1 per 100,000) is much lower than the population-based estimate (320 per 100,000) suggests that there me be under-reporting of facility deaths and/or a substantial proportion of deaths occurring in the community. Can you comment on how this will inform the next steps? 7. Following on from this, is there any reliable data on maternal mortality in the community? e.g. through verbal autopsy component that you mention (page 3, line 22) ? The fact that the second most common cause of death was obstructed labour should be highlighted as reason to consider mortality and morbidity in the community, as lack of access to to delivery in a health facility is a significant risk factor for obstructed labour. 9. Can you clarify on page 10, line 13-14, that malaria is third most common in all patient populations (rather than obstetric populations) 10. Your study shows great success in improving reporting of maternal deaths throughout the five-year period, as shown by increased reporting (including abortion-related deaths) and decreasing missing data - likely a sign of acceptance by clinicians. It would be useful to discuss in greater details the facilitators and barriers to implementing the MDA programme and any lessons learnt that may be useful for other settings.

VERSION 1 – AUTHOR RESPONSE

Comments by Reviewer #1:

Type	Reviewer comment	Author response
General remarks	This is an interesting paper examining a relatively large number of maternal deaths. I think the purpose of the paper needs clarifying somewhat: is it aiming to provide a profile of the characteristics of maternal deaths in Rwanda: at the moment it just describes the findings, without analysing whether these are representative for all deaths within the country. Otherwise it is generally clear and the findings well presented.	Thank you for these kind words. We have slightly altered the phrasing of the study objective (in the abstract only), which is to ... “present the results of five years of implementing health facility-based maternal death audits in Rwanda”. In the discussion we point out that there “could be ... underreporting of maternal deaths through HMIS” and “ there may be other maternal deaths that happened in the community and these are neither captured in the HMIS, nor by audits”.
Introduction	The introduction needs a section on the benefits of MDA, and experiences within other contexts.	We have expanded the last phrase of the first paragraph of the Introduction section. It now reads as follows: “Maternal death audit is one of the

		strategies that have proven effective to improve the quality of obstetric care in Ethiopia, Nigeria and Senegal, and there are indications that the audits have helped reduce maternal mortality."
	There also needs to be more contextual information about maternal health care in Rwanda, and how this has changed in the five years covered by the study.	We have added the following paragraph to the Introduction section (as second paragraph): "More than 90% of all deliveries in Rwanda nowadays take place in health centres and are assisted by trained health workers. Women who are detected with high-risk pregnancies are advised to deliver at the nearest district hospital. Those who are referred and in the possession of a community health insurance card pay a reduced fee when they deliver at a district hospital. Rwanda has 30 district hospitals that each serve a population of 200,000-350,000 and provide emergency obstetric care."
Methods	More details are needed on the maternal death audits, and in particular how cause of deaths was ascertained and assigned. Was ICD 10 classification used? Was cause of death taken from patient's notes, and if so what level or cadre of health care provider provided the diagnosis? Was it discussed and in appropriate modified during the committee meeting?	We have clarified who establishes the cause of death in the first instance. And we have added the following sentence: "When auditing a maternal death, the committee reviews and sometimes further specifies the cause of death recorded in the patient notes. The cause of death is reported in narrative form, without necessarily using the ICD-10 classification."
Findings	The section on substandard factors associated with the deaths is rather disappointing. The category "poor case management" is very broad – can it not be broken down more? It would be interesting to try and bring out a few of key concerns and link them with recommendations: at the moment they are placed in separate tables and you cannot see how one leads to another. Alternatively maybe a joint table could be produced with both factors and recommendations linked? Were there some "headline messages" that could be taken from this?	One of the limitations of the maternal death audits in Rwanda is that the audit committees report substandard care in their own words (as shown in Box 2), without being very specific in most instances about what exactly was not up to standard in individual case management. Ministry of Health authorities recognise that the template used to audit cases requires improvement. The recommendations made by the audit committees (in Box 1) are a bit more specific, for instance with regard to certain aspects of obstetric case management. Nevertheless we have refrained from putting frequency counts for each of the recommendations, as the data set is not sufficiently robust to do so. For the same reason, a joint table that would link reported factors (Box 2) with recommendations made (Box 1) is not feasible. Your observation is pertinent though, and this has led us to expand on one of the bullet points in the list of Strengths and limitations of the study (in the Abstract),

		and a short phrase in the Discussion section. We are now saying: • (in the Abstract:) "Five years of MDA implementation in Rwanda provides a huge body of evidence on causes of death, substandard service factors and recommendations made to reduce the chance of reoccurrence, even though the occurrence of various forms of substandard case management and systemic flaws remains not entirely clear." (please note: only the underlined part has been added) • (at the end of the Discussion section): However, there is room to improve the template used in Rwanda to audit and report maternal deaths; in particular the precise inadequacies in poor obstetric case management would need to be spelt out in greater detail, which could help the audit teams to come up with remedial actions that are more concrete.
Discussion	There needs to be much more discussion on the possible limitations of your study (and the methods used to gather the data). Presumably diagnosis relies on HCP diagnosis – this may be flawed due to poor diagnostic ability or limited opportunity in cases where death occurs very soon after admission. Induced abortion may be under-reported due to failure of patients and their families to provide relevant information. Changes over time may not just reflect real trends, but may reflect increased awareness of particular conditions due to training etc.	Diagnostic capacity is limited indeed, so the diagnosis that health workers establish and report may not be correct. And conditions such as induced abortion may indeed be underreported, and end up being reported as haemorrhage or infection. We have now addressed this in the Discussion section (in the one but last paragraph) by saying: "Some of the changes observed over time, however, may not reflect real trends, because of inadequate diagnostic capacity, underreporting of induced abortion as a cause of death, or increased awareness of a particular condition following training and/or closer monitoring."
	You recognise that your study excludes deaths occurring in the community, but you don't outline how this will potentially bias your results. It will potentially mean that estimates around cause of death, avoidable health system / community factors will be not reflect the full national situation and this should be discussed.	We have added the following to the Discussion section (2nd paragraph): "One could assume that the direct and indirect causes of death, and the role of community versus service factors, among cases that do not get notified are different from the picture that emerges from the maternal death audits." We further point out that in order to get a clearer idea of the full national situation we are now suggesting (in the Conclusions section of our paper) to: (a) link results from verbal autopsy to the MDA results; and (b) adopt two additional methods (i.e. confidential enquiry into maternal deaths and near-miss audit) as complements to

		MDA.
	I think the findings need to be discussed within the context of health systems changes in Rwanda during this time.	We have added to the Discussion (end of 1st paragraph): "Maternal death audits as a nation-wide strategy in Rwanda, is part of a much broader package of interventions aimed at improving maternal and child health indicators and strengthening the national health system as a whole. These include national-level support to a dense network of community health workers, community-based health insurance, the use of ICT and mobile telephones for performance monitoring, and performance-based financing, among others." We have added three references (nrs 21,22,23) to this effect.

Comments by Reviewer #2:

Type	Reviewer comment	Author response
General comments	Thank you for this interesting and informative article on maternal death reviews in Rwanda. This is an important piece of work, in an area where few articles reflect the experience in low-income settings. As a country which has shown great success in work towards achieving the Millennium Development Goals, it is important that lessons learnt and interventions implemented are shared and disseminated. The authors experiences and results from implementing maternal death audits will be valuable for other countries looking to reduce maternal mortality. I suggest this manuscript is accepted for publication with consideration of the following suggestions and comments.	Thank you for accepting and the kind words.
Methods	1. The strength of the methods used and the interpretation of trends will depend heavily on the processes used to define and identify maternal deaths. In particular, it is worth referring to the processes (if any) used to identify deaths outside of the maternity units. You refer to this briefly being the case after 2011 (p4, line 51-52) but it would be useful to know how this was done. This will affect the number of deaths reported during early pregnancy and beyond the puerperium, or due to indirect causes, which are often missed.	We acknowledge that health facility-based maternal death audits do not provide the full picture. We are saying (2nd paragraph of the Discussion) that there could be "... underreporting of maternal deaths through HMIS, especially before 2011, when only deaths that occurred in maternity departments were reported." We are also saying (same paragraph) that: "In addition, there may be other maternal deaths that happened in the community and these are neither captured in the HMIS, nor by audits." Immediately following this latter sentence, we have now added: "One could assume that the direct and indirect causes of death, and the role of community versus service factors, among

		cases that do not get notified are different from the picture that emerges from the maternal death audits." We further point out that in order to get a clearer idea of the full national situation we suggest (in the Conclusions section of our paper) to (a) link results from verbal autopsy to the MDA results; and (b) adopt two additional methods (i.e. confidential enquiry into maternal deaths and near-miss audit) as complements to MDA.
	2. Does the health management information system and/or the maternal death audit programme cover private facilities or facilities run by NGOs, faith-based organisations etc? Please comment on this is the methods section.	Both the HMIS and the maternal death audit system cover all health facilities: Government-owned, as well as private and church-related hospitals (owned by faith-based NGOs). We have now clarified this in the methods section, in two different places (for MDA committees and HMIS, respectively.
	3. Similarly, with regards to the cause of death, it is worth clarifying the processes used to arrive at the cause of death (e.g. consensus, expert opinion, case definitions, post mortem) or to acknowledge if this was determined at the local level.	We have clarified that the health staff on duty at the time of death (which may be a doctor, a nurse or midwife) establishes the cause of death in the first instance, and writes it in the patient notes. And we have added (in the Methods section) the following sentence: "When auditing a maternal death, the committee reviews and sometimes modifies the cause of death recorded in the patient notes. The cause of death is reported in narrative form, without necessarily using the ICD-10 classification."
	4. There is no mention of research ethics, or whether confidentiality was maintained for patients and/or clinicians involved during the review process	We have now clarified that in the methods section, by saying: "Confidentiality of both the patient and the clinician is maintained during the auditing process. The standard form that is used and the reports that are submitted to the Ministry of Health do not indicate any names; and the protocol stipulates that 'no one should be blamed'."
Results and Discussion	5. If possible, it would be useful to comment on the characteristics of cases that were not identified through MDA but were reported through HMIS. Do you know how they differ from the cases that were audited?	Unfortunately for us as researchers , but for very good reasons (confidentiality!), the HMIS reports only numbers. So it is not possible to establish whether all the audited cases were reported through the HMIS or whether some cases were missed and vice versa.
	6. You state that only 4.6% of women identified in the MDA delivered at home, which may be misconstrued as encouraging home births. Please clarify in results (page 6, line 12) and discussion (page 9, line 39) that this only refers to women who delivered at home and died in a facility. The proportion of women who deliver at home and die at home has not been enumerated, and cannot be commented on.	That is a very good point. To avoid any misinterpretation we are now saying in the 3rd paragraph of the revised version: "The fact that only 4.6% of the women who died delivered at home does not warrant any conclusions about home deliveries as a risk factor."

	7. As you righty comment (page 9, lines 8 -14), the fact that the facility-based MMR (69.1 per 100,000) is much lower than the population-based estimate (320 per 100,000) suggests that there me be under-reporting of facility deaths and/or a substantial proportion of deaths occurring in the community. Can you comment on how this will inform the next steps?	In order to get a clearer idea of the full national situation – both in terms of numbers of cases of maternal death and direct/indirect causes – we are now suggesting in the Conclusions section of our paper to: (a) link the results from verbal autopsy to the MDA results; and (b) adopt two additional methods (i.e. confidential enquiry into maternal deaths and near-miss audit), complementary to MDA.
	7.(→8) Following on from this, is there any reliable data on maternal mortality in the community? e.g. through verbal autopsy component that you mention (page 3, line 22) ? The fact that the second most common cause of death was obstructed labour should be highlighted as reason to consider mortality and morbidity in the community, as lack of access to to delivery in a health facility is a significant risk factor for obstructed labour.	It is true that access to obstetric care, especially emergency obstetric care, is limited; this is both for financial reasons and because of physical distance. We are doing more research work in Rwanda, and we hope to soon publish the results of case study research that we conducted in May-June this year in 4 different districts, where we conducted focus group discussions with service providers and community health workers about maternity care: service quality and access issues. For reliable figures about the occurrence of maternal death in the community we will have to wait for the 2015 DHS results to come out. As we indicated in the Discussion section: "We may expect a much lower proportion of home deliveries in the next DHS, due in 2015" (i.e. lower than the 31% found in the 2010 DHS). We are also expecting a reduction in MMR over the past 5 years.
	9. Can you clarify on page 10, line 13-14, that malaria is third most common in all patient populations (rather than obstetric populations)	We have clarified this as follows: "The fluctuation in maternal deaths due to malaria can be attributed to the general variation in morbidity due to malaria in the whole population. The number of confirmed malaria cases treated in health facilities rose steeply between 2012 and 2013; malaria was the third most frequent cause of death in 2013 (7.2%) among the general population and also the third most important cause of morbidity among outpatients at health facilities (10.6%).[28]
	10. Your study shows great success in improving reporting of maternal deaths throughout the five-year period, as shown by increased reporting (including abortion-related deaths) and decreasing missing data - likely a sign of acceptance by clinicians. It would be useful to discuss in greater details the facilitators and barriers to implementing the MDA programme and any lessons learnt that may be useful for other settings.	We start our Conclusions section by saying: "Maternal death audit can be implemented routinely and nationwide even in low-income countries as shown by the high coverage of maternal deaths audited in Rwanda." We have now added: "There do not seem to be major barriers among clinicians and other health

		workers to conduct audits and investigate the possible role of systemic or incidental flaws in service delivery." For your information (not included in this paper): we are planning to publish an article on challenges and lessons learnt in implementing maternal death audits.

VERSION 2 – REVIEW

REVIEWER	Sarah Neal University of Southampton
REVIEW RETURNED	18-Dec-2015

GENERAL COMMENTS	I am happy with the revisions made based on my earlier review