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)	Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care
AUTHORS	Lazzerini, Marzia; Senanayake, H.; Mohamed, Rishard; Kaluarachchi, Athula; Fernando, Roshini; Sakalasuriya, Anshumalie; Ihsan, Fathima Reshma; Saravanabhava, Namasivayam; Gamaathige, Nalin; Jayawardena, Madura; Gamage, Ruwan Vidana; Covi, Benedetta; Wanzira, Humphey; Businelli, Caterina; Piccoli, Monica

VERSION 1 – REVIEW

REVIEWER	Abigail Beane Mahidol Oxford Research Institution. Bangkok, Thailand. Academic Medical Centre, University of Amsterdam.
REVIEW RETURNED	13-Jun-2018

GENERAL COMMENTS	Review This manuscript profiles a working collaboration between clinicians in South Asia and Europe and the authors should be commended for their collaborative approach to describing their ambition for continuous granular data collection in obstetric health. Please consider the following two points as significant limitations in the current manuscript. It is not clear to the reader what the primary aim or research question is. The authors initially describe the objective of the study as being 'to pilot, in the largest maternity unit in Sri Lanka, a system for collecting prospectively, for each case of delivery, a wide number of variables reflecting maternal and newborn characteristics,' The authors then go on to describe a set of aims extending to 'exploring the feasibility of such system, the quality of data collected, and the concrete uses of data to improve quality of healthcare' The first objective described is clear and is met by the information reported. The 'aims' subsequently described are not currently met by the results reported and are perhaps extremely ambitious at this stage of the work described. 2. The results reported do not currently support these extensive aims. For example, 'feasibility' - an increasingly utilised and relevant term investigators working through the broad lens of implementation

science, especially in resource-limited settings - needs careful consideration. In the context of an individual real-world patient database for quality improvement, exploration of feasibility would, in keeping with current literature, need to consider factors such as baseline availability of data to be collected, the burden of data collection, resource requirements and costs.

In addition, it is difficult to see how the recommendations for improvement in the manuscript arise directly from the surveillance data. By the authors own admission 'exploration of concrete uses of data to improve quality of healthcare' is not addressed within the context of what is currently reported, and at present appears beyond the scope of the work described.

Recommendations.
Perhaps the authors would consider narrowing their focus to the initial objective of reporting a pilot data collection, as this is very topical and a timely topic given the current global health agenda for understanding quality of care, and in developing systems to strengthen information for both individual care and for facility level service evaluation.[1,2]

The authors describe the ability to collect 'a wide number of variables reflecting maternal and newborn characteristics, hospital practices and outcomes.' They later reflect on the challenges of narrowing this data set and in aligning collaborator priorities- a valuable insight. Declaring the primary research question(s) or aim would enable the reader to understand the direction of the work and evaluate the merits of the recommendations for improvement made.

For example, a prospective evaluation of the appropriateness (against reference criteria) of elective CS in an LMIC tertiary care centre? If however, these are not current, but potentially focus questions for a prospectively collected data collection/audit in a sustainable manner using routinely available data, then perhaps it is best to approach in that manner.

If the authors agree with the above and wish to narrow the objectives and consider feasibility as the focus of their manuscript, the following points may be warranted for consideration.

3.1 How were the data points decided by the collaboration?
Would be helpful to the reader and those interested in establishing similar systems how the collaboration when about deciding on the data set and scope of surveillance.

3.2 As the collaboration are reporting on the piloting of a digital database, would they be able to explain why an intermediate paper-based system was used?
There is growing evidence that such tools can have a positive impact on stakeholders through engagement, user empowerment and enabling information to be used in real time for clinical decision making and to help close the loop of feedback. Why was the data not extracted from the notes? Were data fields absent in the case records extracted from elsewhere (important for feasibility etc…)

3.3 Perhaps the authors could give a more summarised selection and demonstrate how the data captured would be used/

disseminated on a practical level to enable the change process?
In addition, how would the database be used to evaluate the impact of proposed improvements? For example, how would process measures be described or changes in clinician decision-making be evaluated.3

3.4 How was the collaboration formed?
The development of an international collaborative for a local database is an important step in addressing existing information availability bottlenecks in LMIC health systems.
It would be of interest to the reader and would provide context for the research questions if the authors could elaborate on the motivation for the collaboration.

3.5 Where there concerns over data collection, security and storage? If yes, how did the collaboration address these concerns?
One of the most dominant challenges of implementing registries, and data collection for service evaluation in all settings, but with often greatest emotivity in LMICs is data security and storage.
How did the leads for the collaboration address these issues? E.g how did they obtain hospital permission?

English.

There are some inconsistencies in English. Some minor corrections have been offered through this review. I would suggest following the specific objectives above being addressed, the author group have the manuscript read through for English grammar by a native English speaker.

References.

Biccard BM, Madiba TE, Kluyts HL, Munlemvo DM, Madzimbamuto FD, Basenero A, Gordon CS, Youssouf C, Rakotoarison SR, Gobin V, Samateh AL. Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. The Lancet. 2018 Jan 3.
Dare AJ, Onajin-Obembe B, Makasa EM. A snapshot of surgical outcomes and needs in Africa. The Lancet. 2018 Apr 21;391(10130):1553-4.
Snyder, Claire F. et al. "THE ROLE OF INFORMATICS IN PROMOTING PATIENT-CENTERED CARE." Cancer journal (Sudbury, Mass.) 17.4 (2011): 211–218. PMC. Web. 13 June 2018.

REVIEWER	Amy Gray University of Melbourne, Royal Children's Hospital, Murdoch Children's Research Institute. Australia
REVIEW RETURNED	20-Jun-2018

GENERAL COMMENTS	This is an important but simply presented paper which illustrates both the logistical aspects of routine patient-level data in a low-resource setting and the basic outcomes of the data. Examples of this kind are important. The overall writing of the publication however contains numerous spelling and grammar issues and will benefit from a thorough review for language. Some of the identifiable errors

are listed below.

Introduction - is appropriate, justifies study
Methods - relatively simple methods are well described except for the description of the use for quality improvemnet processes "any action-orientated type of use". THis is a very vague statement. Would it be better to describe this as "any action-orientated recommendation generated from review of the data outcomes by researchers and partners..etc.

Results - I am concerned about way data is expressed in Table 3. The heading for column 2 includes an n=7504 yet the percentages expressed in the table in relation to CS rates in Robson groups clearly does not relate to same "n" value ie 246/7504 is not 16%. IF there is a different demoninator here it needs to be made clear. Same for CS rates. The format of this table needs to be reviewed.

Results otherwise seem appropriately reported.

Discussion is appropriate

The conclusion could also reference the need to understand how recommendations generated from data are best translated into practice.

Specific comments regarding spelling or grammar errors
1. Line 26 pg 4 "No technical problem was reported"
2. Line 28 pg 4 " Data completeness exceeds..."
3. Line 12 page 5 "can produce a large quantity of reliable..."
4. Line 9 page 6 "recommended"
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	of...over time. Data generated...
	31. Line 19 pg 32 maternity units...
	32. Line 32 pg 32, project timelines it was not able to follow up the impact of the recommendations developed...

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Abigail Beane
Institution and Country: Mahidol Oxford Research Institution. Bangkok, Thailand. Academic Medical Centre, University of Amsterdam.
Please state any competing interests or state 'None declared': None declared.
Please leave your comments for the authors below
Thank you for the opportunity to review this manuscript 'Implementation of an individual-patient prospective database of hospital births in Sri Lanka and its use for improving quality of care'.

Review
This manuscript profiles a working collaboration between clinicians in South Asia and Europe and the authors should be commended for their collaborative approach to describing their ambition for continuous granular data collection in obstetric health.
*** Many thanks for your appreciation

Please consider the following two points as significant limitations in the current manuscript.

It is not clear to the reader what the primary aim or research question is.
The authors initially describe the objective of the study as being 'to pilot, in the largest maternity unit in Sri Lanka, a system for collecting prospectively, for each case of delivery, a wide number of variables reflecting maternal and newborn characteristics,'
The authors then go on to describe a set of aims extending to 'exploring the feasibility of such system, the quality of data collected, and the concrete uses of data to improve quality of healthcare'
The first objective described is clear and is met by the information reported. The 'aims' subsequently described are not currently met by the results reported and are perhaps extremely ambitious at this stage of the work described.
**This has been corrected, the word feasibility has been deleted.

2. The results reported do not currently support these extensive aims.
For example, 'feasibility' - an increasingly utilised and relevant term investigators working through the broad lens of implementation science, especially in resource-limited settings - needs careful consideration. In the context of an individual real-world patient database for quality improvement, exploration of feasibility would, in keeping with current literature, need to consider factors such as baseline availability of data to be collected, the burden of data collection, resource requirements and costs.
In addition, it is difficult to see how the recommendations for improvement in the manuscript arise directly from the surveillance data. By the authors own admission 'exploration of concrete uses of data to improve quality of healthcare' is not addressed within the context of what is currently reported, and at present appears beyond the scope of the work described.
Recommendations.
Perhaps the authors would consider narrowing their focus to the initial objective of reporting a pilot data collection, as this is very topical and a timely topic given the current global health agenda for understanding quality of care, and in developing systems to strengthen information for both individual care and for facility level service evaluation.1,2
**This has been corrected and clarified. In practice, the study aimed at piloting both the system of data collection, and in reporting the use of data for developing recommendations to improve the

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quality of maternal and newborn care. Following indication on the second reviewers, we have better clarified what we meant for "exploration of concrete uses of data to improve quality of healthcare". Actually we meant "any action-oriented recommendation generated from review of the data outcomes by researchers and partners". We believe that the section on data use is actually very important, since the project was conceived with this specific objective, ie, collecting data and using them for developing recommendation to improve quality of care. Routine use of data to improve case management and organization of care is still not a common practice, even in countries with well-established data collection systems, and we believe that this section is crucial. This has now been further clarified in the manuscript.

The authors describe the ability to collect 'a wide number of variables reflecting maternal and newborn characteristics, hospital practices and outcomes.' They later reflect on the challenges of narrowing this data set and in aligning collaborator priorities- a valuable insight. Declaring the primary research question(s) or aim would enable the reader to understand the direction of the work and evaluate the merits of the recommendations for improvement made.
For example, a prospective evaluation of the appropriateness (against reference criteria) of elective CS in an LMIC tertiary care centre? If however, these are not current, but potentially focus questions for a prospectively collected data collection/audit in a sustainable manner using routinely available data, then perhaps it is best to approach in that manner.
**This has been better clarified, using the recommendations provided by both reviewers. Variables were selected, based on the experience reported in the literature and on previous experience of the team, so that it could allow answering different research questions and monitoring trends over time. The choice of using a relatively large number of variables to allow different types of analyses is in line with what performed in other similar experiences of establishing data collection systems. As already stated in the paper, this is a first report on the descriptive analysis of the content of the database (see method section on "data analysis and use)". Two more analyses are ongoing, exploring CS as for the Robson classification, and exploring practices related to IOL. These findings will be the object of future publications, as reported in the discussion section.

If the authors agree with the above and wish to narrow the objectives and consider feasibility as the focus of their manuscript, the following points may be warranted for consideration.

3.1 How were the data points decided by the collaboration?
Would be helpful to the reader and those interested in establishing similar systems how the collaboration when about deciding on the data set and scope of surveillance.
*** This sentence was not entirely clear to us. However:
- a clarification on the establishment of the collaboration, and on the agreement about the scope of the surveillance has been added in the method section;
- a clarification on how the variables were selected has been added in the method section;
- precise case definitions were developed during the initial workshops, and embedded in the data collection form, as already reported in the method section.

3.2 As the collaboration are reporting on the piloting of a digital database, would they be able to explain why an intermediate paper-based system was used?
There is growing evidence that such tools can have a positive impact on stakeholders through engagement, user empowerment and enabling information to be used in real time for clinical decision making and to help close the loop of feedback. Why was the data not extracted from the notes? Were data fields absent in the case records extracted from elsewhere (important for feasibility etc…)
***All relevant information were extracted from the medical files. The use of an intermediate paper based system was agreed at the beginning of the project for the following reason: using an form to collect data allow to check internal consistency in the data collected, before entering them in the database.

This information has been added in the paper.

3.3 Perhaps the authors could give a more summarised selection and demonstrate how the data captured would be used/ disseminated on a practical level to enable the change process?
*** Additional information on how data collected were disseminated and used have been added in the paper, in the section "data analysis and use".

In addition, how would the database be used to evaluate the impact of proposed improvements? For example, how would process measures be described or changes in clinician decision-making be evaluated.3
***This has been added and clarified in the discussion section.

3.4 How was the collaboration formed?
The development of an international collaborative for a local database is an important step in addressing existing information availability bottlenecks in LMIC health systems.
It would be of interest to the reader and would provide context for the research questions if the authors could elaborate on the motivation for the collaboration.
***Previous collaborations among the involved institutions provided the opportunity. This has been further clarified under "population and setting"

3.5 Where there concerns over data collection, security and storage? If yes, how did the collaboration address these concerns? One of the most dominant challenges of implementing registries, and data collection for service evaluation in all settings, but with often greatest emotivity in LMICs is data security and storage. How did the leads for the collaboration address these issues? E.g how did they obtain hospital permission?
***The project was submitted to the Ethical board of the hospital .Rules of GCP were followed. Confidentiality was maintained by de-identifying all files before database entry.

English.
There are some inconsistencies in English. Some minor corrections have been offered through this review. I would suggest following the specific objectives above being addressed, the author group have the manuscript read through for English grammar by a native English speaker.
** The paper has been revised by an English speaker

References.
Biccard BM, Madiba TE, Kluyts HL, Munlemvo DM, Madzimbamuto FD, Basenero A, Gordon CS, Youssouf C, Rakotoarison SR, Gobin V, Samateh AL. Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. The Lancet. 2018 Jan 3.
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Reviewer: 2
Reviewer Name: Amy Gray
Institution and Country: University of Melbourne, Royal Children's Hospital, Murdoch Children's Research Institute. Australia
Please state any competing interests or state 'None declared': None declared

This is an important but simply presented paper which illustrates both the logistical aspects of routine

patient-level data in a low-resource setting and the basic outcomes of the data. Examples of this kind are important. The overall writing of the publication however contains numerous spelling and grammar issues and will benefit from a thorough review for language. Some of the identifiable errors are listed below.
*** Thanks for your appreciation

Introduction - is appropriate, justifies study
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Methods - relatively simple methods are well described except for the description of the use for quality improvemnet processes "any action-orientated type of use". THis is a very vague statement. Would it be better to describe this as "any action-orientated recommendation generated from review of the data outcomes by researchers and partners..etc.
*** This was clarified as suggested

Results - I am concerned about way data is expressed in Table 3. The heading for column 2 includes an n=7504 yet the percentages expressed in the table in relation to CS rates in Robson groups clearly does not relate to same "n" value ie 246/7504 is not 16%. IF there is a different demoninator here it needs to be made clear. Same for CS rates. The format of this table needs to be reviewed.
**This has been corrected and clarified. We have opted for reporting only Robson groups, in the text (a complete analysis following the WHO Manual on the Robson classification will be the object of a future publication)

Results otherwise seem appropriately reported.
*** Thanks for your appreciation

Discussion is appropriate
*** Thanks for your appreciation

The conclusion could also reference the need to understand how recommendations generated from data are best translated into practice.
*** This has been added as suggested

Specific comments regarding spelling or grammar errors
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VERSION 2 – REVIEW

REVIEWER	Abi Beane Mahidol, Oxford Research Unit and Network for Improving Critical care Systems and Training.
REVIEW RETURNED	18-Oct-2018

GENERAL COMMENTS	Needs support with editing for English language, consistency of terminology and typesetting.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Abi Beane
Institution and Country: Mahidol, Oxford Research Unit and Network for Improving Critical care Systems and Training.
Please state any competing interests or state 'None declared': none

Please leave your comments for the authors below
Needs support with editing for English language, consistency of terminology and typesetting.
*** The paper has been duly proofread by a native English speaker prior to resubmission.