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The Lancet Small Vulnerable Newborn Series: Guidelines to Enable a Healthy Start --Manuscript Draft--

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Author Comments:	Dear Professor Horton
	Thank you for considering this correspondence for publication in the Lancet, in response to the announcement of the Lancet Small Vulnerable Newborn Series. We believe the call for new reporting guidelines for perinatal studies will be of interest to the readership and support the call for global multidisciplinary approaches to research in maternal, fetal and newborn health.
	We have listed and included author forms for eight co-authors, as we all made a significant contribution to this letter. Within our new iPOP (international Perinatal Outcomes in the Pandemic) Consortium we are keen to clearly demonstrate that we are committed to a team science approach, so would like all the contributors to be recognised on the correspondence if at all possible.
	Yours Sincerely

The Lancet Small Vulnerable Newborn Series: Guidelines to Enable a Healthy Start

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As co-leads of the new international Perinatal Outcomes in the Pandemic (iPOP) Consortium¹ we are delighted that the Small and Vulnerable Newborn Series² will focus cross-sector attention on the high burden of baby deaths (encompassing miscarriage, stillbirth and neonatal mortality) and disability (following preterm birth and low birthweight), which remains largely intractable with current siloed approaches.

iPOP, spanning 38 countries (and welcoming new collaborators¹), brings expertise in perinatology, epidemiology, environmental science, intersectional feminism, and data science³ within a collaborative, equitable and interdisciplinary framework. iPOP will investigate the effects of pandemic lockdowns on key perinatal outcomes, leveraging this natural experiment to understand possible mechanisms and inform interventions and policy. Conceptualisation of perinatal outcomes as a continuum, rather than discrete endpoints, is essential to this effort. The new Lancet Series is a timely initiative to catalyse this paradigm shift in the approach to perinatal research globally.

More generally, new reporting guidelines are needed to capture the complexity of perinatal studies, enabling assessment of data plausibility and completeness, and encouraging methodology which encompasses multiple (and competing) outcomes. Consensus guidance will support scientists, clinicians, reviewers and journal editors, driving up standards of research to benefit women and children. A pervasive culture remains that some perinatal data are too hard to collect and certain classifications of baby deaths (miscarriages, stillbirths) are less important to document. We call for standardised guidance for studies of perinatal outcomes as part of the Small and Vulnerable Newborn Series, to improve data quality, challenge these misconceptions, and support research transparency.

2

References

- International Perinatal Outcomes in the Pandemic (iPOP). Available from: www.ipopstudy.com (Accessed (24th September 2020)
- Ashorn P, Black RE, Lawn JE, Ashorn U, Klein N, Hofmeyr J, Temmerman M, Askari S. The Lancet Small Vulnerable Newborn Series: science for a healthy start. Lancet. 2020 Sep 12;396(10253):743-745.
- International COVID-19 Data Research Alliance and Workbench. Available from: <u>https://www.hdruk.ac.uk/covid-19/international-covid-19-data-alliance/</u> (Accessed 24th September 2020)

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Declaration of interests

Sarah Stock reports grants from Wellcome Trust and Health Data Research UK, during the conduct of the study. Helga Zoega reports grants from AbbVie Australia outside the submitted work. Aziz Sheikh reports grants from Health Data Research UK, during the conduct of the study.

Author Contributions

JVB, AS, MBA, SJS, HZ, MB and DB contributed to the conception of the letter. SJS, MB, HZ, DB and MBA drafted the letter. ZAB, SJS, MB, HZ, MBA, JVB, AS and DB edited the letter. ZAB, SJS, MB, HZ, MBA, JVB, AS and DB all approved the final version to be published. SJS, MB, HZ, DB and MBA are co-leads of iPOP.