

Published Online October 27, 2020 https://doi.org/10.1016/ S0140-6736(20)32235-2 For the **iPOP Consortium** 

see www.ipopstudy.com

For the International COVID-19

Data Alliance see https://www.
hdruk.ac.uk/covid-19/
international-covid-19-dataalliance/

For the COVID-19 Therapeutics Accelerator see https://www. therapeuticsaccelerator.org/



Published Online October 19, 2020 https://doi.org/10.1016/ S0140-6736(20)32177-2

It appears that since January, 2020, after Uluq and Powell's results were made available on ClinicalTrials.gov, ClinicalTrials.gov has made specific material available on reporting units other than participants, which might be helpful to the authors. Additionally, ClinicalTrials.gov provides a free-text section on limitations and caveats, in which irregularities and additional context can be added to results for review and interpretation by users. The authors might now be able to further update their results and provide a more complete account of their trial. However, we believe that edge cases such as these are unlikely to explain the high rates of non-compliance reported in our analysis,4 and would probably not be viewed as a valid reason for not reporting if any enforcement action is taken against a non-compliant sponsor under the

NJD receives a doctoral studentship from the Naji Foundation and grant funding from the Fetzer Franklin Memorial Fund. BG has received research funding from the Wellcome Trust, the National Health Service (NHS) National Institute for Health Research, the NHS National Institute for Health Research School of Primary Care Research, the Oxford Biomedical Research Centre, the Mohn-Westlake Foundation, the Health Foundation, and WHO. BG also receives personal income from speaking and writing for lay audiences on the misuse of science and is a co-founder of the AllTrials Campaign. The TrialsTracker Project is funded by the Good Thinking Foundation and was previously funded by the Laura and John Arnold Foundation

## \*Nicholas J DeVito, Ben Goldacre nicholas.devito@phc.ox.ac.uk

Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford OX2 6GG, UK

- DeVito NJ. Results reporting on ICTRP registries: a cross-sectional audit study. Feb 25, 2020. https://osf.io/xenkq/ (accessed Sept 29, 2020).
- 2 Cyranoski D. China's coronavirus vaccines are leaping ahead-but face challenges as virus wanes. Nature 2020; 584: 17-18.
- 3 US National Library of Medicine. Training materials. https://clinicaltrials.gov/ct2/ manage-recs/present#ResultsExamplStudies (accessed Aug 21, 2020).
- 4 DeVito NJ, Bacon S, Goldacre B. Compliance with legal requirement to report clinical trial results on ClinicalTrials.gov: a cohort study. *Lancet* 2020; 395: 361–69.

## Enabling a healthy start for vulnerable newborns

As co-leads of the new international Perinatal Outcomes in the Pandemic (iPOP) Consortium, we are delighted that the *Lancet* Small Vulnerable Newborn Series¹ 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 remain largely intractable with current siloed approaches.

iPOP, spanning 38 countries (and welcoming new collaborators), brings expertise in perinatology, epidemiology, environmental science, intersectional feminism, and data science (supported by the International COVID-19 Data Alliance, an initiative funded by the COVID-19 Therapeutics Accelerator) 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. A 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 that encompasses multiple (and competing) outcomes. Consensus quidance 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 that 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 *Lancet* Small Vulnerable Newborn Series,<sup>1</sup> to improve data quality, challenge these misconceptions, and support research transparency.

SJS, MB, HZ, DPB, and MBA are co-leads of iPOP. SJS reports grants from the Wellcome Trust and Health Data Research UK. HZ reports grants from AbbVie Australia, unrelated to this Correspondence. AS reports grants from Health Data Research UK. All other authors declare no competing interests.

\*Sarah J Stock, Meredith Brockway, Helga Zoega, Jasper V Been, Aziz Sheikh, Zulfiqar A Bhutta, David P Burgner, Meghan B Azad sarah.stock@ed.ac.uk

University of Edinburgh Usher Institute, Edinburgh EH16 4UX, UK (SJS, AS); Children's Hospital Research Institute of Manitoba, Departments of Pediatrics and Child Health & Community Health Sciences, University of Manitoba, Winnipeg, MB, Canada (MB, MBA); Centre for Big Data Research in Health, Faculty of Medicine, UNSW Sydney, Sydney, NSW, Australia (HZ): Centre of Public Health Sciences, Faculty of Medicine, University of Iceland, Iceland (HZ); Division of Neonatology, Department of Paediatrics, Erasmus MC-Sophia Children's Hospital, University Medical Centre Rotterdam, Rotterdam, Netherlands (JVB); Centre for Global Child Health, The Hospital for Sick Children, Toronto, ON, Canada (ZAB); Institute for Global Health and Development, Aga Khan University, Karachi, Pakistan (ZAB); Murdoch Children's Research Institute, Royal Children's Hospital, Parkville, VIC, Australia (DPB): and Department of Paediatrics, University of Melbourne, Parkville, VIC, Australia (DPB)

1 Ashorn P, Black RE, Lawn JE, et al. The Lancet Small Vulnerable Newborn Series: science for a healthy start. Lancet 2020; 396: 743–45.

## **Department of Error**

Alwan NA, Burgess RA, Ashworth S, et al. Scientific consensus on the COVID-19 pandemic: we need to act now. Lancet 2020; **396:** e71–72— The appendix of this Correspondence has been corrected as of Oct 19, 2020.

Jeger RV, Farah A, Ohlow M-A, et al. Long-term efficacy and safety of drug-coated balloons versus drug-eluting stents for small coronary artery disease (BASKET-SMALL 2): 3-year follow-up of a randomised, non-inferiority trial. Lancet 2020; 396: 1504-10—In this Article, Florian Krackhardt and Robert Zweiker should have been included in the list of BASKET-SMALL 2 investigators. In table 2, the footnote "\*Hazard ratios are for DCB vs DES" has been added. These corrections have been made to the online version as of Nov 5, 2020, and the printed version is correct.