research

New 11 item checklist for reporting abstracts of diagnostic accuracy studies p 269

Improved survival and reduction in cerebral palsy in children born at 25-34 weeks in France p 270

One in five infants born small for gestational age in low and middle income countries p 270

RESEARCH METHODS AND REPORTING

Essential items for reporting diagnostic accuracy studies in journal or conference abstracts

STARD for Abstracts

Cohen JF, Korevaar DA, Gatsonis CA, et al for the STARD Group

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Many abstracts of diagnostic accuracy studies are insufficiently informative. This makes it difficult for readers to assess the validity and applicability of the study findings and to decide whether they should obtain the full journal article or attend the conference presentation. To improve the informativeness of journal and conference abstracts of diagnostic accuracy studies, the reporting guideline STARD for Abstracts was developed as an extension to the STARD (Standards for Reporting Diagnostic Accuracy) statement, an internationally accepted reporting guideline for diagnostic accuracy studies. The authors determined a list of essential items that should be considered when reporting diagnostic accuracy studies in journal and conference abstracts. Out of 39 potentially relevant items identified through a literature review, the authors selected essential items through a two round web based survey among the 85 members of the STARD Group. This group brings together methodologists, statisticians, journal editors, and other stakeholders with expertise in the evaluation of medical tests. Seventy three members of the STARD Group responded to the survey (86%), with 100% completion rate. A draft list was produced after the survey; the list was then fine tuned by discussions within an executive committee. STARD for Abstracts presents a list of 11 essential items to be reported in every abstract of a diagnostic accuracy study. Journals or organisations could ask for additional information and authors may incorporate other STARD 2015 elements in their abstract, including a flow diagram. The authors also provide examples of complete reporting and template text for writing informative abstracts in the full paper on bmj.com.

STARD for Abstracts: essential items for reporting diagnostic accuracy studies in journal or conference abstracts

Section	Item
	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)
Background and objectives	Study objectives
Methods	Data collection: whether this was a prospective or retrospective study
	Eligibility criteria for participants and settings where the data were collected
	Whether participants formed a consecutive, random, or convenience series
	Description of the index test and reference standard
Results	Number of participants with and without the target condition included in the analysis
	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)
Discussion	General interpretation of the results
	Implications for practice, including the intended use of the index test
Registration	Registration number and name of registry

AUC=area under the curve.
Key STARD terminology: index test=the test under evaluation; target condition=the disease, disease stage, event, or condition that the index test is expected to detect; reference standard=the test or procedure used for establishing the presence or absence of the target condition; intended use of test=whether the index test is used for diagnosis, screening, staging, monitoring, surveillance, prediction, prognosis, or other reasons.

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The online version is published along with peer and patient reviews for the paper, and a statement about how the authors will share data from their study. It also includes a description of whether and how patients were included in the design or reporting of the research.

The linked commentaries in this section appear on bmj.com as editorials. Use the citation given at the end of commentaries to cite an article or find it online.

ORIGINAL RESEARCH EPIPAGE-2 cohort study

Neurodevelopmental outcome at 2 years for preterm children born at 22 to 34 weeks' gestation in France in 2011

Pierrat V, Marchand-Martin L, Arnaud C, et al and the EPIPAGE-2 writing group

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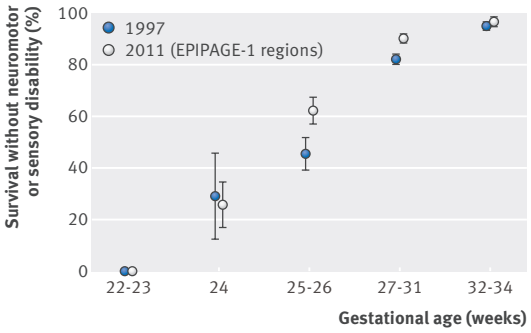
Study question What is the neurodevelopmental outcome at 2 years corrected age for children born in France in 2011 between 22 and 34 weeks' gestation, and how has this changed since 1997?

Methods Participants were from the French national population based cohort studies, EPIPAGE-1 (1997) and EPIPAGE-2 (2011). In 2011, 5567 neonates were born alive during the study period and 4199 survivors were included in follow-up. Main outcome measures were overall survival and survival without severe or moderate neuromotor or sensory disabilities at 2 years corrected age (cerebral palsy with Gross Motor Function Classification System levels 2-5, unilateral or bilateral blindness or deafness) and scores below threshold on the neurodevelopmental Ages and Stages Questionnaire (ASQ)—completed by parents of children without cerebral palsy, blindness, or deafness. Information on cerebral palsy was available for 3599 children (81.0%) and ASQ data were available for 2506 children (56.4%). Outcomes in 2011 were compared with 1997 for children included in the nine regions participating in both studies.



Comparison of survival rates without severe or moderate neuromotor or sensory disabilities (ie, survivors without Gross Motor Function Classification System levels 2-5, unilateral or bilateral blindness or deafness) at 2 years corrected age in the nine French regions participating in both EPIPAGE-1 (1997) and EPIPAGE-2 (2011). Results based on data including multiple imputation

ORIGINAL RESEARCH Analysis of CHERG datasets

Estimates of burdens and consequences of infants born small for gestational age and attributable neonatal deaths in low and middle income countries with INTERGROWTH-21st standard

Lee ACC, Kozuki N, Cousens S, et al for the CHERG Small-for-Gestational-Age-Preterm Birth Working Group

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Find this at: http://dx.doi.org/10.1136/bmj.j3677

Study question How many liveborn infants would be classed as small for gestational age with the new INTERGROWTH-21st birthweight standard, how many neonatal deaths would be attributable to being small for gestational age, and how many such deaths could be prevented by reducing the prevalence of small for gestational age to 10%?

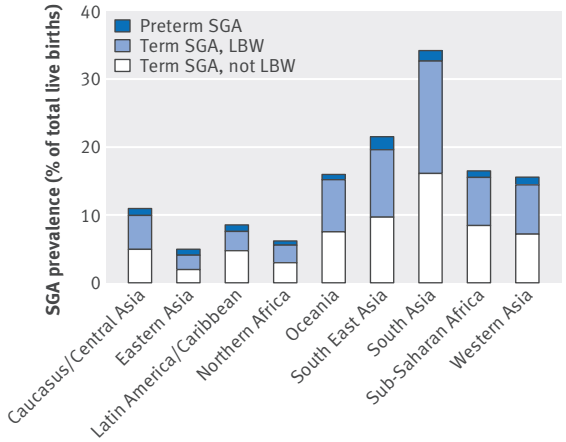
Methods This was a secondary analysis of data from the Child Health Epidemiology Reference Group, including 14 population based birth cohorts from low and middle income countries, with data on gestational age, birth weight, and neonatal follow-up. Small for gestational age was defined as weighing less than the 10th centile of birth weight for gestational age and sex based on the multiethnic INTERGROWTH-21st standard. Prevalence and neonatal mortality risk ratios were calculated and pooled among these datasets at the regional level. Using available national level data, the authors calculated the prevalence of infants born small for gestational age and estimated the population attributable fractions of neonatal mortality attributable to small for gestational age in the year 2012.

Study answer and limitations With the INTERGROWTH-21st standard, an estimated 23.3 million infants (19.3% of live births) were born small for gestational age in low and middle income countries in the year 2012. Among these, 11.2 million were term and not low birth weight (≥2500 g), 10.7 million were term and low birth weight (‹2500 g), and 1.5 million were preterm. An estimated 606 500 neonatal deaths were attributable to small for gestational age, 21.9% of all neonatal deaths. The highest burden was in South Asia, where the prevalence (34%) was highest and 26% of neonatal deaths were attributable to small for gestational age. Reduction of the prevalence of small for gestational age from 19.3% to 10.0% in these countries could reduce neonatal deaths by 254 600. Limitations to these estimates include the availability and

Study answer and limitations Between 25 and 31 weeks' gestation, rates of survival and survival without severe or moderate neuromotor or sensory disabilities increased during the past two decades. The incidence of cerebral palsy was reduced at all gestations greater than 24 weeks. In the EPIPAGE-2 cohort, the proportions of children with an ASQ result below threshold at 24-26, 27-31, and 32-34 weeks' gestation were 50.2% (95% confidence interval 44.5% to 55.8%), 40.7% (38.3% to 43.2%), and 36.2% (32.4% to 40.1%), respectively. The main limitation was the number of children lost to follow-up. Therefore, multiple imputation was used to account for missing data.

What this study adds Improvement in survival was accompanied by a reduction in incidence of cerebral palsy in children born at 25-34 weeks' gestation. Between one third and one half of children, dependent on gestational age, were identified through the use of parental questionnaires as requiring formal developmental evaluation.

Funding, competing interests, data sharing This study was supported by the French Institute of Public Health, the French National Research Agency, and other foundations. The authors report no competing interests. Data sharing policies for the EPIPAGE studies are available from http://epipage2.inserm.fr/index.php/en.



Prevalence of infants born small for gestational age (SGA) among live births in low and middle income countries in 2012, by UN-MDG region. LBW=low birth weight (<2500 g)

quality of data on birth weight and gestational age in low and middle income countries.

What this study adds In low and middle income countries, around one in five infants are born small for gestational age, and a similar proportion of neonatal deaths are among such infants. While these estimates are lower than prior estimates with the 1991 US reference population, there is still a large burden to target for prevention and interventions in these countries.

Funding, competing interests, data sharing The study was funded by the Bill & Melinda Gates Foundation. There are no competing interests to declare and no data to share.

The wastage of unpublished research globally

Paul Glasziou and **Iain Chalmers** discuss the validity that half of all research is never published

If 50% of mail we posted never arrived, the outcry would be considerable. Although current estimates are that about half of research goes unpublished, there is little outcry. Maybe that is because the results of research projects are not addressed to a specific person who would notice when they hadn't arrived; or maybe some think the situation isn't as bad as implied by the 50% estimate.

Rates of publication have been documented best for clinical trials, particularly since trial registration at inception became more widespread over the past 20 years. In the 1980s and 1990s estimates of trial publication rates were derived from retrospective cohort studies of trial proposals submitted to ethics committees, and from specialist trial registers. In this century, however, mandated registration of trials has enabled much larger cohorts of trials to be investigated.

So is the 50% estimate still true for trials with the increased expectations of registration and reporting? And because trials constitute only a small proportion (2%-3%) of all biomedical studies, is the 50% figure true for other types of research?

Discordant methods

The key obstacle to answering these questions is knowing about all the unpublished research—research's "dark side of the moon." At least three methods have been used to estimate the proportion of unpublished studies, using as denominators cohorts of all studies: studies seen by specific ethics committees, studies presented at specific conferences, or studies pre-registered in registries. None of these methods capture all studies—not all studies require ethical approval, not all are presented, and few have to be registered. In summary, all methods tend to underestimate the non-publication rate. An overview by Schmucker and colleagues (*PLoS One* 2017;doi:10.1371/journal.pone.0114023) of 17 cohorts of studies approved by research ethics committees found that, on average, 46% were published; and among analyses of 22 studies included in trial registries it was found that, on average, 54% were published. In summary, slightly less than half of the studies (trial and non-trial) approved by ethics committees had been published, and slightly more than half

of pre-registered controlled trials had been published.

Some of the studies reviewed by Schmucker and colleagues were quite old however—so do those estimated publication rates still apply? Well, the most relevant recent large study by Chen and colleagues (*BMJ* 2016;i637) found similar results: of the 4347 clinical trials registered in ClinicalTrials.gov, 2458 (56.5%) had been published and 2892 (66.5%) had been either published or results reported without journal publication. The 10% that were reported but not formally published in journals is noteworthy. Chen and colleagues found that 27% had results reported on ClinicalTrials.gov, which provides fields and support for such reporting (and is mandated for US trials). So the bad news is that the rate of publication in journals seems unchanged, but the good news is the results of an additional 10% are available in trials registries. TrialsTracker (https://trialstracker.ebmdatalab.net/#/) is attempting to automate the monitoring of publication rates and provides a breakdown by sponsor. Its current analysis of 29 377 eligible trials found a 55% publication rate (that is, 45% missing).

Maybe it's only small or poor studies that go unpublished? The best analysis of that possibility found that rates varied little by country, size of trial, or trial type. Unfortunately, the best predictor of publication seems to be whether the study is "positive" or "negative," which means that the half of the research results we can access is biased. So there is both waste and distortion.

For animal studies, and other preclinical studies, we know much less, both because study registries are rare and because mandatory ethics clearance is patchy. A survey of animal researchers has reported that they thought that 50% were unpublished, but little direct evidence exists.

Implications of non-publication

Whether the precise non-publication rate is 30%, 40%, or 50%, it is still a serious waste of the roughly £138bn ($180bn; €153bn) annually invested in health and medical research globally. Non-publication means that researchers cannot replicate or learn from the results found by others—particularly the disappointments, which are less likely to be published. Funders deciding on the gain from new research cannot base that decision on all previous research. Reviewers trying to summarise all the research addressing a particular question are limited by access only to a biased subsample of what has been done.

Although there has been some modest progress in reducing biased under-reporting of research, efforts are still needed to ensure that all trials are registered and reported, and to extend those principles to all studies. A prerequisite for achieving these objectives will be a better understanding of the causes of, and cures for, non-publication.

PS Despite the considerable avoidable waste in medical research, from non-publication and other causes, investment in biomedical research is cost effective and serves the interests of the public. Working to reduce waste to improve the return on investment is important, however, and should not be used as a reason to reduce support for medical research, as proposed by the US president, Donald Trump, earlier this year but sensibly rejected by Congress.

Paul Glasziou is professor of evidence based medicine at Bond University and a part time general practitioner

Between 1978 and 2003, Iain Chalmers helped to establish the National Perinatal Epidemiology Unit and the Cochrane Collaboration. Since 2003 he has coordinated the James Lind Initiative's contribution to the development of the James Lind Alliance, the James Lind Library, Testing Treatments interactive, and REWARD.

Competing interests: IC declares his NIHR salary, which requires him to promote better research for better healthcare.