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# Why data sharing is important for children

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Evidence-based medicine is recognised as the way of ensuring individual patients receive the correct diagnosis and treatment and that health systems ensure that appropriate treatments are provided to communities. Evidence-based medicine is especially important in children where many medicines are used in an off-label manner. Evidence-based medicine should result in the more rational use of medicines in children.[1]

Medical journals provide researchers with a location for their research. Peer review alongside editorial input is used in order to ensure that researchers' findings are presented and interpreted objectively. This is essential for the generation of objective evidence. *BMJ Paediatrics Open* ensures that the peer review process is transparent by publishing the reviewers' names, their comments and previous versions of the articles. All articles alongside the peer review comments are available to both health professionals and the public, free of charge. We recognise that not all individuals have access to the internet and that in many low and lower middle-income countries internet availability for health professionals and researchers is often intermittent or difficult to access.

Data sharing—the provision of the original research data for each scientific study is not a new idea, but is increasingly being recognised as being important.[2] Researchers involved in systematic reviews are well aware that many scientific papers do not adequately explain and present all their findings. Systematic reviews are an important step in drawing up evidence-based guidelines. It is well recognised that adverse drug reactions are inadequately reported in clinical trials. This is especially so in paediatric patients.[3] Additionally, clinical trials involving children and adults do not always present the paediatric data separately and this is disadvantageous to the paediatric population. In a systematic review of randomised clinical trials of antiepileptic drugs in children, 29 trials involved children and adults.[3] However, only 10 stated the actual number of children recruited and only 3 analysed the paediatric patients separately. Consolidated Standards of Reporting Trials guidelines have helped to improve the reporting of clinical trials. They do not however insist on the separate presentation and analysis of different population subgroups such as children. Such information should always be included in the paper. The provision of the original data will allow investigators to access this information.

There have also been cases where clinical trial data have been misinterpreted and subsequent reanalysis of the original data finds different findings. An example of this is the reanalysis of trial data for paroxetine in the treatment of major depression in adolescents.[4] The original trial was published in 2001 and suggested that paroxetine was effective in the treatment of adolescent major depression.[5] An independent reanalysis of the data published in 2015 found no evidence of efficacy.[4] Authors often have preconceived ideas about efficacy and safety and will overstate findings to try and ensure both publication and impact. The provision of original data will allow reanalysis to ensure that the interpretation by the authors is correct. A gap of 14 years is unacceptable, both scientifically and ethically. The young people who participated in the original trial did so to help ensure others received the most beneficial treatment.

There are also other examples where the interpretation of data varies. This results in guidelines which differ in their recommendations. There are significant differences in the recommendations for the diagnosis and management of asthma between the National Institute for Health and Care Excellence guideline and the collaborative guideline from the British Thoracic Society and the Scottish Intercollegiate Guideline Network.[6] Similarly, different countries have

different guidelines for eating disorders.[7] Recently a Cochrane review on human papillomavirus vaccine[8] was criticised for its interpretation of the data.[9] These examples show that the interpretation of data is complex, and researchers and health professionals need access to original data to ensure patients receive optimal treatment.

We are therefore strongly encouraging authors to ensure that the data on which their research paper is based are made available. Details of what data should be stored and how to store it are available in our instructions to authors. In brief data must be anonymised and provided in sufficient detail to allow others to reanalyse the data and confirm the author's findings. There are well-established controlled access repositories where researchers can deposit data.

For clinical trials, data must be made available on reasonable request. Individuals requesting the relevant data need to provide a detailed protocol for their proposed study and also to consider inviting the original authors to participate in the reanalysis. Guidance regarding data from clinical trials has been previously published and authors should refer to this article.[10]

For clinical trials that begin enrolling children on or after 1 January 2019, a data-sharing plan must be included alongside trial registration. This will result in compliance with the International Committee of Medical Journal Editors recommendations.[11]

We are confident that data sharing will become readily accepted by the research community and hopefully also result in greater collaboration between researchers. It should also ensure that all research becomes publicly available and that children of all ages receive the best possible management and treatment.

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**Patient consent** Not required.

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