

Pilot and feasibility studies – more than just measuring metrics

We congratulate Charlesworth et al. [1] on their excellent study evaluating the conversion and reporting of pilot studies published in six major anaesthesia journals and would like to make a few comments.

A substantial proportion of public funds are invested in medical research, particularly randomised controlled trials, which are regarded as the most powerful methodology to assess new interventions. It is therefore disappointing that only 56% of randomised controlled trials funded by National Institute for Health Research Health Technology Assessment (HTA) programme trials reach their final recruitment target [2]. Previous literature has suggested that pilot and feasibility studies, when correctly labelled and conducted to high standards, add value to successfully delivering large scale cost-effectiveness trials. Conversely, they may also demonstrate that a definitive trial is not possible which is equally important for minimising research waste [3]. The work by Charlesworth et al. is an important addition to this literature as they have demonstrated that correctly labelled pilot or feasibility studies were more likely to lead to a full conversion study.

We would also like to highlight that pilot and feasibility studies offer an excellent opportunity for qualitative research and process evaluation. These approaches can provide vital information for ensuring acceptability of participation for patients, their carers (if appropriate) and clinical staff. A recent study used the views of parents of critically ill children to devise a trial on fluid bolus therapy in children with septic shock. Parents made recommendations about the timing of research discussion, the content of a participation information sheet and personalising postal 'opt-out' approaches for consent [3]. Such valuable information may be missed from studies purely focusing on recruitment metrics, and useful guidance for incorporating qualitative research in feasibility studies is now available [4].

The authors speculate that pilot and feasibility studies may be seen as low priority publications but there is evidence that this may be changing, with feasibility trials now being published in high impact factor journals [5]. The creation of a dedicated journal, *Pilot and Feasibility Studies*, which is now listed on PubMed, is also a welcome step forward.

What are the next steps? Funding bodies should have dedicated funding streams for pilot and feasibility studies, or there should be an expectation that pilot work will have been carried out prior

to a large trial. Avery et al. advocate the use of a pre-specified 'traffic light' system to determine progression for pilot studies [5]. This is a positive step towards informing efficient trials and minimising research waste. Lastly, the 'three Ps' (person, project and place) are often mentioned as the key ingredients for a successful grant application. We argue that there needs to be a fourth P – pilot/feasibility work.

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Competing interests

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References

1. Charlesworth M, Klein AA, White SM. A bibliometric analysis of the conversion and reporting of pilot studies published in six anaesthesia journals. *Anaesthesia* 2020; **75**: 247-53.
2. Avery KN, Williamson PR, Gamble C, et al. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *British Medical Journal Open* 2017; **7**: e013537.
3. Inwald D, Canter RR, Woolfall K, et al. Restricted fluid bolus versus current practice in children with septic shock: the FiSh feasibility study and pilot RCT. *Health Technology Assessment* 2018; **22**: 1-106.
4. O'Cathain A, Hoddinott P, Lewin S, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot and Feasibility Studies* 2015; **1**: 32.
5. Moller A, Nielsen HB, Wetterslev J, et al. Low vs high hemoglobin trigger for transfusion in vascular surgery: a randomized clinical feasibility trial. *Blood* 2019; **133**: 2639-50.