

## **Clinician equipoise on applied research**

### **A position statement from the NIAA founding partners**

#### ***What is applied health research?***

Medical research holds significant value for patients, health professionals and society. Advancing understanding of disease processes and therapeutic interventions ultimately leads to a healthier and more prosperous society. In addition to the huge range in medical research topics (e.g. different diseases), there are also many different types of research. For most members of the public, medical research is about developing new drugs, first in the laboratory and then in clinical trials where these are compared to placebo. This is commonly known as translational research. Applied health research does not focus on developing new therapies but on establishing which existing treatments work the best. This usually means we compare the benefits and harms of two or more treatments that are already widely used in the NHS and elsewhere. This kind of research accounts for a large part of the health research taking place in the UK. It involves finding out what treatments work best for patients, how much these cost, and how they can be delivered at scale.

#### ***What is equipoise?***

There is now good evidence that research active hospitals deliver better quality healthcare<sup>1,2,3</sup>. For individual patients, participation in research is not only a priority but a right. The NHS constitution sets ambitious targets for patient participation in research<sup>4</sup> and the National Institute for Health Research has built substantial infrastructure throughout the NHS to ensure this is possible. However, the task of providing opportunities to participate in research is complex and depends on whether the patient is suitable for those studies which are recruiting. Healthcare professionals have a duty to facilitate patients' participation in research but they are also responsible for ensuring this is appropriate for them. In particular, doctors have an important duty to ensure their patient is safe. Significant problems arise when researchers fail to properly handle safety issues in their clinical trials, but also when doctors misrepresent clinical prejudice as safety concern. In some cases, doctors may believe they already know the answer to a trial question, and so insist either on using the trial treatment in every patient, or not using it at all. A recent striking example was provided by the RECOVERY trial of

treatments for COVID-19 which was made an urgent public health priority and strongly promoted by the chief medical officers of all four devolved nations. Many NHS doctors heeded this call and supported the trial but some felt sure they already knew the answers. This resulted in the widespread use of treatments which were subsequently shown to be ineffective (eg hydroxychloroquine) and the refusal to prescribe drugs which saved lives (eg dexamethasone). This problem is not just confined to a handful of clinical trials. One recent study showed that participation in a randomised trial comparing two acceptable treatments is almost always a less popular option than choosing one of the treatments based on pre-existing knowledge and belief<sup>5</sup>. Poor clinician equipoise doesn't only affect individual patients. Anecdotally, this problem appears to represent a major barrier to successful delivery of major clinical trials, making them slow to provide answers to urgent questions and expensive to conduct. This has a negative impact on patient and society.

### ***Statement***

A positive research culture within medicine is necessary to ensure all patients have the opportunity to participate in safe clinical trials. Understanding and ensuring clinician equipoise is an essential part of this culture. The founding partners of the National Institute of Academic Anaesthesia (NIAA) agree on the following statements:

- Individual patients have the right to participate in safe clinical trials. This opportunity should be supported and promoted by treating clinicians. Patients should be allowed to make their own decision about taking part in research.
- Inequity in access to research means a patient's opportunities to participate are often determined by which hospital they are treated in. This variation is not acceptable.
- Objective research is needed to understand clinician equipoise towards randomised trials and the challenges this creates for researchers. In particular, we need to understand the balance between a clinician's concerns about patient safety and their pre-existing views about the clinical effectiveness of trial treatments.
- This research should inform the development of solutions which are widely acceptable to the perioperative care community.

## References

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