

## ■ INFOGRAPHIC

# Decision-making in surgical study designs: a proposed decision algorithm to aid in the selection of an appropriate research study design for a given surgical intervention: the PERFECT tool



**A. H. R. W. Simpson,  
N. S. Makaram,  
E. Harrison,  
J. Norrie**

From University of  
Edinburgh, Edinburgh,  
UK

**Cite this article:** *Bone Joint Res* 2023;12(9):598–600.

**Keywords:** PERFECT, Trial, Explanatory, Pragmatic, Registry

High-quality clinical research in surgery is characterized by randomized controlled trials (RCTs)<sup>1,2</sup> and large registry-based investigations.<sup>3–5</sup> Trial design is a nuanced technique and requires careful thought. For example, if the clinician chooses to investigate a newly introduced intervention with a pragmatic RCT to estimate its effectiveness (how it works in the real world), without having first established its efficacy (the effect of the intervention under ideal conditions), then even if the pragmatic trial finds the intervention to be ineffective, this finding cannot be relied upon – we cannot know whether this finding is because the intervention is not effective, or because the delivery is not effective.<sup>6–8</sup> It would therefore be more beneficial to identify whether the intervention is efficacious (with an explanatory trial), and to identify which sources of variation may influence outcome (such as learning curve,<sup>6,9</sup> case-volume, and case-mix<sup>10</sup>) prior to embarking on a pragmatic trial. The PRagmatic-Explanatory Continuum Indicator Summary-2 (PRECIS-2) tool is a helpful aid indicating that the domains of a trial can vary between being explanatory or pragmatic in nature.<sup>1</sup> The IDEAL framework<sup>11</sup> for new techniques aids clinicians in deciding which surgical study design would be most appropriate based on the stage of development of a new surgical device/innovation. However, it does not encompass the comparison of existing surgical techniques, or established surgical and non-surgical treatments. For established techniques, registries or large datasets may exist. The power of existing data should also not be underestimated – appropriate use of existing datasets

and pooled analyses (systematic reviews or meta-analyses) can be invaluable in deciding whether a trial is required, and/or what type.<sup>10</sup> Registries can also help to determine the type of study that would be suited for investigation of an intervention, based on the source of variation identified: if the variation is at the patient level, the next step may be to carry out a pragmatic trial, however if these datasets show large variation in the surgical care systems involved in procedure administration, then reorganization of the system, using a quality improvement approach, may be preferred.<sup>10,12</sup> Surgery should be considered a complex intervention, and quality improvement necessitates meaningful engagement with patients, practitioners, and policy-makers, ensuring that research moves beyond binary questions of effectiveness, to whether interventions can be safely implemented in an acceptable and cost-effective manner, scaling across settings and populations.<sup>13</sup> The National Institute for Health and Care Research (NIHR)/Medical Research Council (MRC) complex intervention framework provides guidance that should be more broadly applied in surgical settings.<sup>13</sup> Our infographic (PERFECT – Pragmatic, Explanatory, Registry Framework for sElection of Clinical Trial format) provides a proposed decision tool for selecting the appropriate study design for the intervention-based research question for treatments already in current practice.

## Twitter

Follow A. H. R. W. Simpson @ahrwsimpson and @BoneJointRes

Correspondence should be sent to  
A. Hamish R. W. Simpson; email:  
hamish.simpson@ed.ac.uk

doi: 10.1302/2046-3758.129.BJR-  
2023-0232

*Bone Joint Res* 2023;12(9):598–  
600.

## References

- Loudon K, Tweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M.** The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015;350:h2147.
- Ghert M.** The reporting of outcomes in randomised controlled trials: the switch and the spin. *Bone Joint Res*. 2017;6(10):600–601.
- Yapp LZ, Clement ND, Moran M, Clarke JV, Simpson AHRW, Scott CEH.** The estimated lifetime risk of revision after primary knee arthroplasty is influenced by age, sex, and indication. *Bone Joint J*. 2022;104-B(12):1313–1322.
- Baker PN, Jeyapalan R, Jameson SS.** The value of national arthroplasty registry data in 2023. *Bone Joint J*. 2023;105-B(4):356–360.
- Berry DJ.** Joint registries: what can we learn in 2016?. *Bone Joint J*. 2017;99-B(1 Suppl A):3–7.
- Simpson AHRW, Howie CR, Norrie J.** Surgical trial design - learning curve and surgeon volume: Determining whether inferior results are due to the procedure itself, or delivery of the procedure by the surgeon. *Bone Joint Res*. 2017;6(4):194–195.
- Makaram NS, Lamb SE, Simpson A.** Are we doing the right surgical trials? *Bone Joint Res*. 2023;12(6):372–374.
- Makaram NS, Simpson A.** Explanatory and pragmatic trials in orthopaedics - Have we done the right studies? *Injury*. 2023;110905.
- Zhang J, Ng N, Scott CEH, et al.** Robotic arm-assisted versus manual unicompartamental knee arthroplasty. *Bone Joint J*. 2022;104-B(5):541–548.
- Simpson AHRW, Frost H, Norrie J.** Pragmatic surgical studies: are they the New Gold Standard. *Bone Joint J*. 2018;100-B(11):1407–1408.
- McCulloch P, Altman DG, Campbell WB, et al.** No surgical innovation without evaluation: the IDEAL recommendations. *Lancet*. 2009;374(9695):1105–1112.
- Briggs T.** A national review of adult elective orthopaedic services in England: Getting It Right First Time. British Orthopaedic Association. 2015. <https://gettingitrightfi>  
rsttime.co.uk/wp-content/uploads/2018/07/GIRFT-National-Report-Mar15-Web.pdf (date last accessed 4 September 2023).
- Skivington K, Matthews L, Simpson SA, et al.** A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. *BMJ*. 2021;374:2061.

### Author information:

- A. H. R. W. Simpson, MA(Cantab), BM, BCh (Oxon), DM(Oxon), FRCS(England & Edinburgh), FIORs, Professor of Trauma and Orthopaedics
- N. S. Makaram, MSc, MRCS (Ed), Specialty Registrar Edinburgh Orthopaedics, Royal Infirmary of Edinburgh, Edinburgh, UK; University of Edinburgh, Edinburgh, UK.
- E. Harrison, PhD, FRCS, Professor of Surgery and Data Science, Director, Centre for Medical Informatics, Usher Institute, University of Edinburgh, Edinburgh, UK.
- J. Norrie, BSc, MSc, Professor of Medical Statistics, Director, Edinburgh Clinical Trials Unit, Usher Institute, University of Edinburgh, Edinburgh, UK.

### Author contributions:

- A. H. R. W. Simpson: Conceptualization, Writing – original draft, Writing – review & editing.
- N. S. Makaram: Writing – original draft, Writing – review & editing.
- E. Harrison: Writing – review & editing.
- J. Norrie: Writing – review & editing.

### Funding statement:

- The authors received no financial or material support for the research, authorship, and/or publication of this article.

© 2023 Author(s) et al. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (CC BY-NC-ND 4.0) licence, which permits the copying and redistribution of the work only, and provided the original author and source are credited. See <https://creativecommons.org/licenses/by-nc-nd/4.0/>

# Decision-making in surgical study designs

**A PROPOSED DECISION ALGORITHM TO AID IN THE SELECTION OF AN APPROPRIATE RESEARCH STUDY DESIGN FOR AN EXISTING SURGICAL INTERVENTION: (Pragmatic, Explanatory, Registry Framework for selection of Clinical Trial format - PERFECT)**

