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The Knee

Editorial

Avoiding 'Fake News' in orthopaedic research – measuring the right outcomes and their interpretation

This edition of *The Knee* is a typical delight. In it, there is a spectrum of novel, interesting and informative clinical academic works to inform and inspire. A recurrent theme across this edition and others is that of measurement and how we, as a clinical and/or academic community, determine whether an intervention merits clinical consideration or not.

To determine whether an intervention should be implemented, a number of key parameters should be considered. These include considering: the relevance of the population and clinical setting with the reader's own clinical environment and case-load; whether it is feasible to deliver the intervention described; whether the study reports outcomes which are meaningful to the reader (and their patients); and if the size of the intervention's effect is sufficient to change current practice. The latter two points will now be explored.

Clinical trials seek to determine whether treatments are safe and beneficial for patients by comparing their relative effects on outcomes [1]. Results can then be used to drive decisions on whether a treatment under-investigation should be recommended or not. It is therefore essential that outcomes reported in trials are those which are needed by decision-makers, and reflect meaningful measures for patients, clinicians and other stakeholders [2]. Core outcome sets (COS) are developed to ensure that researchers and clinicians understand what these important outcome measures are. A COS is an agreed set of outcomes (domains) which clinical trialists should measure and report in all clinical trials of a specific condition [3]. A COS also includes recommendations on what outcome measurement instrument should be used to measure these core domains [3]. The outcome measures in rheumatology (OMERACT) group are one organisation which work on developing methodologies around COS development [4]. They recommend that all COS should consider the 'core areas' of death, life impact, resource use/economic impact and pathophysiological manifestations, in addition to monitoring for adverse events [3]. All COS should also consider factors which are not the primary objective of the research but may influence the results or the interpretation of the results [3]. These are known as contextual factors [3].

There has been limited uptake of core outcome sets across knee research [5]. This limits the universal reporting of outcomes which are shown to be most useful for stakeholders. Furthermore, measuring a diverse number of outcomes preclude statistical pooling (meta-analysis) thereby impacting on research synthesis. However, there are 'green shoots' of change. Previous COS have demonstrated support for patient reported outcome measures and assessments of domains which impact on individual patient's lifestyles [6]. This edition of *The Knee* reports numerous examples of this. For instance Lim et al [7] compared the outcomes of 70 patients who underwent primary unicompartmental arthroplasty to revision total knee arthroplasty (TKA) compared to 140 patients who underwent primary TKA Outcomes collected including implant usage, complications and patient reported outcome measures on quality of life and function. The primary analysis was implant usage including the use of constraint implants, use of stems and augments, with secondary outcomes of re-operation rate, complications and then patient reported outcome measures. Likewise Mann et al [8] conducted an analysis of gene expression for stiffness following TKA. These researchers also collected data on functional outcomes and quality of life, thereby acknowledging the importance of patient-based domains, in a back-drop of basic science measures. I encourage further awareness of COS and their benefit in reporting research. If adopted, I hope this will have considerable benefit to knee-related research now and in the future.

When interpreting research findings, readers should consider both clinical *and* statistically significant difference. Statistical significance indicates whether a finding can be attributed to chance alone. Clinically significance indicates whether the size of that difference is 'worth-while' or not. Whilst readers generally feel comfortable about supporting or refuting a finding if it is under

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or over a "$p<0.05$" threshold for statistical significance, such 'blunt' cut-points are less obvious in determining clinical significance. Both concepts must be interpreted when clinicians weigh-up whether a new interventions should be adopted or not. In the absence of evidence, the reader is expected to make a judgement on what they believe the minimal value is to warrant a change in practice. This should however have a scientific basis. The basis of clinical significance is difficult to assess and an area where there is limited evidence. In the perfect world, a reader should have evidence to inform what the 'threshold' is in a score to determine whether an analysis has reached clinical significance. However this is not always possible due to current gaps in the evidence-base.

Clement et al [9] have presented such data in their paper on Short Form-12 physical and mental summary scores after TKA. They determined the minimal clinically important difference (MCID), minimal important change (MIC) and minimal detectable change (MDC). Papers such as these are indispensable for clinicians and researchers. They provide a rigorous basis for decisions on implementation of research into practice. Using evidence such as this, clinicians have an evidence-base rationale for determining clinical significance. From a researcher's perceptive, understanding the MCID is incredibly valuable as it provides an important parameter to form sample size calculations. Through this, researchers can develop more accurate estimates on how many people should be recruited onto a trial to demonstrate a statistical difference (if one really exists). This minimises the risk of type 2 statistical error. Through both notions, understanding the interpretative parameters a measurement instrument, such as the Short-Form 12, which is important to patients and all stakeholders and a valuable piece of evidence.

To conclude, as you enjoy this edition of *The Knee*, I invite you to further consider outcome measures, their selection for your patients and how they should be interpreted when reflecting on our own clinical practice.

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