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A Systematic Review Protocol: the Foundation of a High Quality Systematic Review.

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Evidence based healthcare (EBHC) was once defined as being the integration between clinical expertise and the best external evidence.[1] Whilst the foundations of this premise remain true, today's understanding of EBHC has expanded to include factors such as patient preference and the context in which care is to be delivered.[2] Whilst our definitions of EBHC may change over time, the cornerstone of EBHC remains the fundamental need to be informed by the best available evidence.[1-3] Systematic reviews (SRs) remain the highest reporting standard to present this evidence.[4, 5]

An SR that is of high methodological quality, provides a rigorous and unbiased synthesis of relevant studies to summarise the currently available evidence surrounding one highly-specific topic,[6] to be utilised by those at the point of care.[4] However, not all SRs are of high methodological quality, and the subsequent utility of these findings to provide an unbiased, rigorous synthesis of information is compromised.[7] A comprehensive, cross-sectional study identified 682 SRs that were indexed in the MEDLINE database during February 2014, and were specifically asking a therapeutic question. Of this sample, 300 were randomly selected and the quality of their content and reporting was assessed. The authors concluded that the majority of these published SRs were both poorly conducted and reported, and only 16% referenced a publicly accessible protocol; the majority of this sub-set being Cochrane reviews.[7]

This is an interesting finding, as one hallmark that exemplifies an SR of high methodological quality is the development of, and adherence to, an SR protocol.[8] Having a well-written SR protocol reduces the likelihood of authors missing key steps of the review process, using extraction or appraisal tools incorrectly, and inappropriately synthesising the extracted findings.[5] International organisations such as the Joanna Briggs Institute and the Cochrane Collaboration require all SRs to be preceded by a peer-reviewed protocol.[5, 9] Whilst this is not a requirement of all journals willing to publish SRs, there are reasons why reviews linked to these organisations are considered to be some of the highest quality and functionally useful to those at the point of care. Multiple papers have previously described the structure of an SR protocol and provided guidance as to their conduct.[5, 8, 9] The purpose of this editorial is to impress that the protocol is not 'just another step' in the review process, and a published protocol can increase the overall quality of an SR.

Adhering to the same rigorous standards that ensure the SR is informed by the best available evidence, the protocol is the template on which to build an SR of high methodological quality; this starts with the

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framing of a unique question.[6] In 2015, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[10] was extended to the PRISMA protocols (PRISMA-P) statement,[8] to guide reviewers through the process of writing and publishing an SR protocol. Both statements make it clear that a targeted and concise question leads to clear objectives and outcomes for the SR. Using the precise framework recommended for the type of SR being undertaken,[11] exhaustive inclusion and exclusion criteria can be formulated. This provides a set of guiding principles to be followed when selecting studies at title and abstract, and helps to minimise selection bias between reviewers.

When preforming title and abstract article selection, full text review and data extraction, having a protocol available that provides succinct criteria to refer to, can prove invaluable. Issues or concerns that may arise during the review process are considered at this early stage of conception, and may prevent disastrous consequences when it comes to the final stages of review writing. The protocol ensures that independent reviewers base their selection of studies on pre-formulated criteria, helping to prevent arbitrary decision making and selective reporting, consequently leading to higher quality SRs.[12] Authors are bound by the guidance laid forth in their protocol in regards to which papers are to be included or excluded, how methodological quality of these papers is to be assessed and what outcomes and study data are relevant for further analysis. Without such a safety net, these decisions could be rightly queried by the academic community. If as reviewers, we are sceptical of primary research that has been reported poorly, or where the presented results were not aligned with the stated aims and or conclusions, then we must accept that our own reviews should be subjected to the same level of scrutiny.[5]

Whilst the idea of 'establishing methods' before even starting the review process may seem counter-productive to those still dismissive to the utility of protocols, this procedure is critical in reducing the risk of 'reporting bias'. A published protocol prevents decisions made during the review process from being arbitrary.[5, 8] Reviewers may be inclined to report on only some of the information uncovered during the review process, if for example, the size and/or direction of the findings are unexpected, or perhaps one study is distinctly dissimilar in its results. Whilst reporting in this manner is not only morally wrong, the overall findings of a review, for example, the evidence on which EBHC is based, can have profound effects on healthcare and policy-related decisions.[9] Ideally, the final SR should follow the protocol exactly; however, this may not always be possible. As you progress through your SR, there may be legitimate cases in which deviations from your protocol may be necessary. Any deviation from the protocol must be justified and clearly explained in the methods section of the completed SR, in order to maintain this transparency and reduce the risk of reporting bias.[11]

The formalisation of these decisions into a peer-reviewed protocol provides a transparency of process - the cornerstone of scientific method. Finding a journal that will publish the SR protocol requires the same process as finding a journal to publish any research,[13] and although not necessarily the same journal that will publish the SR findings, journals willing to publish protocols will put SR protocols through a peer-review process. The protocol will be peer-reviewed by scholars with expertise in the field of SRs, even before the search is run,[11] and so ensures well-formulated criteria for selection of studies.

Publicly available, peer-reviewed SR protocols can produce subsequent SRs that are of high quality. This high quality hinges on the series of rigorous decisions involved in planning an SR covering eligibility criteria, methodological approach, research integrity, and search criteria, all informing the scientific process.[9] However, few published SRs are accompanied by a published protocol,[7] suggesting that most review authors seemingly 'jump right in' with the start of their review, without undergoing the appropriate

planning and organisation that the rigor of the protocol process facilitates.[12] Despite the increasing requirements to abide by a review protocol from a publishing standpoint, protocols have real, functional benefits that result in higher quality SRs. These include a logical and transparent description of the rationale for undertaking a SR, the research question and hypotheses, inclusion and exclusion criteria as guided by your methodological framework, search strategy, data extraction, quality assessment, and the steps you intend to follow to undertake in your review. Specifying these methods in advance reduces the risk of introducing bias into the review. If review protocols are prepared with guidance, are informed by standards such as PRISMA-P, and have gone through the peer-review process, the resulting SR will be of significantly higher quality than a typical review.[5]

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