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EDITORIAL

Need for greater transparency in documenting informed consent

Kotz et al. in a Commentary [1] call for a re-examination of patient consent in randomised clinical trials. Although informing potential participants about the aims and procedures of a trial is mandatory when seeking their consent, current practice in obtaining informed consent appears to have been shaped the legal duty of disclosure; consent is seen as an action, concluded by signing a form. In line with this administrative attitude toward informed consent, the procedure is standardly reported in a research article. However, there is evidence that the exact information that is given to potential participants is often not understood by them. This is unacceptable, so the authors argue that details about informed consent procedures of randomized controlled trials should be reported transparently with the essential features of the information for participants summarized in the methods section of a trial report and that the full, original participant information letter is published as supplementary material.

Real world data interest continues; with the large data advances in computers we are seeing an explosion of real world evidence analyses. One major issue is that many groups of patients are either excluded from or underrepresented in the clinical trials—data on these is available in administrative data. In this issue Gray et al. [2] provide a thoughtful exposition on the strengths and weaknesses of endpoint effect sizes from a sizable database to contrast with the effect sizes reported in RCTs in patients being treated with adjuvant therapy for breast cancer. They urge caution until the administrative data is shown to be as accurate as that collected in trials.

In a traditional epidemiology cohort study of children in a large and representative UK birth cohort study, Kuda et al. followed the lives of around 17,000 individuals born in Britain during a single week of April in 1970. For this study, data at three times (birth survey, age 10, and at adolescence) were used to identify trajectories of balance development from childhood to adolescence for the first time and to test how these trajectories are conditioned by birthweight. The present findings extend previous research that has demonstrated that higher birthweight is associated with good balance skills in childhood.

Priority setting methods in health research are becoming more formalised and funders are increasingly insisting that these research priorities are demand driven by consumers or the general public or their representatives. However approaches still vary widely—so the scoping review by Nyanchoka et al. is very timely; a nice feature is showing the various formats for presenting the information. It would be worthwhile widening this to include other sectors where similar work is ongoing in education, developmental economics, justice and social sciences [3]. Work is also needed on how best to avoid unnecessary duplication (and hence research waste) and also how evaluate the different approaches to priority setting since some of them require substantial resources. It is now becoming accepted that not only input from researchers, but also meaningful input from patients and the public are essential when deciding on patient–relevant clinically important core outcomes for systematic reviews. Soobiah et al. [4] provide a nice example in selecting outcomes for a systematic review of controlled trials of the effectiveness of a comprehensive geriatric assessment and multidisciplinary management of biomedical, psychosocial, functional, and social capacity of seniors over 65 years of age; thirty-three stakeholder (patients, caregivers, policymakers and geriatricians) participated and achieved consensus over 3 rounds of the Delphi process on recommending that activities of daily living, cognition and quality of life assessments are of greatest import.

Journal impact factor and article citations are known to be poor surrogates for clinical usefulness. Furthermore one can not rely on a few journals to provide sufficient numbers of the most clinically relevant papers for one persons clinical practice. A variety of derivative documents with different approaches attempt to address this. Here Haynes et al. [5] report on the McMaster Premium Literature Service (PLUS), running continuously since 2003 to alert clinicians to quality-assessed, studies and systematic reviews judged by peer clinicians to be clinically interesting. Major findings were that a small set of journals is never enough and even for leading clinical journals, the proportion of articles that are of adequate research merit and high clinical interest is less than 10 percent. In addition to being a useful efficient evidence-based medicine resource for busy clinicians, the authors suggest this may be useful to guide decisions about journal selection and subscriptions by clinicians, professional organizations, and clinical libraries.

The increasing appreciation of multimorbidity issues have stimulated calls for new approaches—for example the 2018 paper on the Joint Action on Chronic Diseases and Promoting Healthy Aging across the Life Cycle (JA-CHRODIS) [6].

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It calls for collection of evidence on the appropriate available integrated and multidimensional care pathways for multimorbid patients focusing on five domains (Delivery of Care; Decision Support; Self Management Support; Information Systems and Technology; and Social and Community Resources). In order to develop the needed evidence-based recommendations specific to multimorbid patients, it is important to identify the most common patterns of comorbidity JCE [7] along with other journals have published some studies that show differing patterns; in this issue Roth et al. [8] in a large database of nearly 200,000 hospital admissions were indeed unable to identify useful clusters since so many patients had clinical characteristics that would not benefit from general recommendations. They conclude that management of multimorbid patients should be individualized and may not be generalized based on a few multimorbidity patterns or clusters.

Two papers address diagnostic tests. Zgodic et al. [9] raise some concerns about the appropriateness of using the random effects results from meta-analyses in assessing different diagnostic test combinations. Using the example of different strategies for diagnosing recurrence in women with breast cancer they provide an algorithm of which estimates from meta-analyses to use. Breheny et al. [10] evaluated 74 studies evaluating point of care diagnostic tests between 2004 and 2017 − the authors argue that these are not useful unless they assess not only test accuracy but also rates of correct diagnosis, testing time, cost-benefit and differences in access to care. Seventy-four model-based evaluations were included: 95% incorporated evidence on test accuracy, but 34% only assessed intermediate outcomes such as rates of correct diagnosis. Of 54 models where Point of Care Tests reduced testing time, 39% addressed the economic and 37% addressed the health benefits of faster diagnosis. No model considered differences in access to tests. The authors suggest that more should be done to ensure that the methods used in model-based economic evaluations adequately consider the impact Point of Care Tests have on diagnostic and treatment pathways through changes in testing setting and timing.

After protocol registration, publishing of systematic reviews meeting the criteria laid out by PROSPERO takes on average over a year and a half. Many commissioners of reviews call for a shortening this process. Marshall et al. [11] report on whether the process can be speeded up by (a) searching PubMed only; (b) limiting search by publication date (cutoffs of 5, 7, 10, 15, and 20 years before search date); (c) limiting inclusion by sample size (minimum of 50, 100, and 200); and (d) using the largest trial only. With the possible exception of limiting the search to PubMed, these result in unacceptably high changes in effect size when the results are to be widely disseminated and subject to judicial review. Reporting on a different approach to speeding up systematic reviews, Bashir and Dunn argue on in a Commentary [9807] that there needs to be more active collaboration between of the systematic review and medical informatics communities, not only for handing individual reviews but for the whole systematic review ecosystem. They recommend urgent attention to expanding the use of standardized data formats for representing trials through their registrations and all forms of reporting including published articles, structured summary results, clinical study reports, and individual participant data. More countries and funding organizations should consider requiring the timely reporting of structured and machine-readable summary results for trials they fund. To meet the current challenges associated with systematic reviews, they recommend renewed focus on new tools and changes in policy that help systematic reviewers do the right systematic reviews at the right time.

Many journals including JCE [12] have articles and editorials calling for the sharing of raw data from trials both for transparency as well as being made available for individual patient data systematic reviews. The article in this issue by Gabelica e al [13] provides another example of the challenge reported by Polanin last year in JCE of the resistance to sharing the raw data; there are ongoing substantive concerns about inappropriate use of publicly available raw data so perhaps the ICJME should take the lead in this as they did with Trial Registration to establish not only mandatory requirements but processes to avoid abuse of this data such as the data only being released on submission of a satisfactory protocol.

Dunn et al. [14] found that industry funded studies get published faster that other studies using two new outcomes (time to inclusion and frequency of inclusion of trials in systematic reviews). This increased speed may not be surprising given the often larger resources available to industry but this does call for this being addressed in an equitable fashion.

Overviews of systematic reviews are attractive documents for those that want to compare and contrast multiple interventions that were individually assessed in different systematic reviews. However Faggion and Diaz [15] found that the definitions of overviews and how each defines what each considers a systematic review, plus their criteria for ensuring reproducibility and comprehensiveness is quite inconsistent. They call for consensus on these.

Yan et al. [16] report on the poor quality of 123 published meta-analyses of robotic surgery for prostate, rectum, bladder, stomach and pancreas conditions. Only 2 meta-analyses met the AMSTAR critieria. There was little difference by country. They suggest the most useful next steps are that all future systematic reviews report funding sources of individual studies and preregister a detailed protocol on an open-source database.

Finally, on a positive note, systematic reviews are beginning to be adopted by an increasing number of countries; it is heartening to see over 100 on topics relevant to Ethiopia in peer review journals reported by Habtewold et al. [9820 [17]]. However although not surprising, many do not yet fulfill best practice quality criteria. The Global Evaluation Synthesis Initiative provides an important forum for such

capacity development (http://www.gesiinitiative.com/gesi-secretariat); this now has over 40 member institutions in lower and middle income countries.

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