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In the second of series of Lower and Middle Income Countries (LMIC) [1], Tulloch-Reid introduces how the clinical epidemiology methodologies have been applied and how they have been adapted to meet the health and healthcare evaluation challenges in the West Indies[8892]. This series reports on the work of the University of the West Indies Clinical Epidemiology Unit (UWI-CEU) in Jamaica, which is a member of the International Clinical Epidemiology Network (INCLEN)/CanUSAClen. This collaboration has increased capacity building in the conduct of clinical epidemiology within the UWI-CEU and their work is highlighted in these articles.

Studies on epidemiological issues in Jamaica are reported, such as the association between neighborhood characteristics and diabetes (Cunningham-Myrie et al.[8695]), completeness of Jamaica’s death registry (McCaw-Binns et al.[8815]), development of a screening questionnaire to detect epilepsy in children (Melbourne-Chambers et al[8840]), the cost of cardiovascular disease risk in Jamaica (Abdulkadri et al.[8832]), and the association between early life characteristics (maternal socioeconomic status and birthweight) and blood pressure amongst young Afro-Caribbean adults (Ferguson et al.[8817]). Challenges specific to the conduct of systematic reviews in Jamaica are discussed by Bennett, including accessibility to the literature, research staff, funding, and knowledge translation issues[8813]. Bennett proposes potential solutions to these challenges, including enhanced collaboration and capacity-building. The history of capacity building in Jamaica for the conduct of clinical epidemiology research is overviewed by Wilks[8814], and the sustainability of this research is discussed, including support from local and international stakeholders, providing career opportunities for early researchers, and identifying long-term funding sources. In front of their Faculty of Medicine in Kingston, Jamaica there is the Savacou [2] sculpture donated by Archie Cochrane in the 1950s, who helped establish the research program at UWI. In June of 2013, one of us (PT) gave a keynote speech at the official launch of The Caribbean Branch of the US Cochrane Center, where he met with the authors of the articles in this series.

Methods used in observational epidemiology studies are constantly developing. de Graaf and colleagues propose a unique way to select a cutoff value that considers the tradeoff between cost per case detected and the detection rate[8893]. An example is summarized using a stepwise screening program to identify pre-diabetes and type 2 diabetes patients by general practitioners. A risk score was calculated for each patient based on 5 items of the Dutch FINDRISC questionnaire for over 5,000 patients. Using these data, the authors found that low cutoff scores increased false-positive results, while high cutoff scores increased false-negative results. In another observational epidemiology methods study, Patel et al look at optimal ways to account for potential confounding variables or effect modifiers[8905]. This is generally achieved through statistical modeling, such as meta-regression analysis. However, the selection of variables in the model and the type of model used is to the discretion of the researchers, who may be inclined to select a model that produces more favourable results. Patel et al. offer a solution that they call the
vibration of effects, which can quantify the variability of results across the selection of numerous variables and models. The authors used the vibration of effects to compute over 8,000 Cox models for exploring the association between each of 417 variables and all-cause mortality. They suggest that studies with larger vibration of effects should be interpreted with caution. Another paper on observational study methods focuses on increasing the ability to predict an outcome of interest (in this case, mortality) by recording secondary diagnoses, complications, and severity of patients be recorded in administrative databases (Yamana et al)[8772]. Using data from the Japanese Diagnosis Procedure Combination database, the authors found that when more diagnosis categories were available for comorbidities, the prevalence of comorbidities increased and the prediction of mortality was improved. The subcategorization of secondary diagnoses, complications, and severity of the main disease allowed for improved modeling of disease burden.

Turning to randomized studies: van Lent and colleagues evaluated the consistency between trial protocols and published reports and found that the inconsistencies they identified were no obstacle to these trials being published in peer-review journals[8762]. They call for editors to check protocols for consistency prior to accepting trial reports for publication. In another paper, Saenz et al. argue that research ethics boards should explicitly review the titles of trials during the conduct of an ethical review[8660]. The reason is that the titles of trials can be misleading. Initiatives from the International Research Panel and Food and Drug Administration that may offer solutions to this issue are highlighted.

A cluster-randomized trial is when centers (e.g., hospitals, clinics) are allocated to the intervention and control groups instead of patients. The Ottawa Statement was the first initiative to guide the ethical and scientific conduct of cluster-randomized trials [3]. Modifications to the Ottawa Statement are proposed by van der Graaf and colleagues in their commentary. Specifically, the authors suggest that although allocation does not occur at the patient level, patients should still be regarded as research subjects[8852]. Care is required when selecting a primary outcome for cluster-randomized trials that target the intervention to health-care workers, because higher attrition may occur amongst these participants. As well, modified informed consent might be necessary if knowledge of participation in the cluster-randomized trial negatively impacts the validity of results due to the potential for contamination. For example, if a behavioural intervention is targeted towards healthcare workers and they discuss the intervention with the healthcare workers in the control group, who decide to implement this change in their practice.

Garfinkle and colleagues conducted an interesting randomized trial to determine whether medical residents were biased by a journal’s prestige[8714]. Fifty medical residents were asked to appraise the quality of two randomized trial abstracts; one was methodologically rigorous and the other had methodological limitations. The residents were randomly assigned to abstracts with the New England Journal of Medicine (a high impact journal) versus Clinical and Investigative
Medicine (a less common journal) journal mastheads. The authors found that the ratings of the abstracts were similar, regardless of the journal masthead.

A randomized trial attempts to ensure that the patient characteristics between the treatment and control groups are balanced. However, sometimes randomization does not work and important imbalances in patient characteristics between groups occur. In order to account for such imbalances, covariate adjustment can be used. Thompson et al [8741] used two large trial datasets to conduct numerous simulations of various sample sizes for covariate adjustment. They found that covariate adjustment led to increased power. As well, the discordance in statistical significance was similar regardless of the sample size for adjusted versus unadjusted results.

Now turning to systematic reviews of randomized trials: Reveiz and colleagues showed that the risk of bias in RCTS has improved over time![8655] They examined the risk of bias of results from 1,732 randomized clinical trials from 97 systematic reviews. In a multivariate logistic regression analysis, the authors found that randomized trials published between 2006 and 2012 had a greater likelihood of scoring a low risk of bias for important domains (sequence generation, allocation concealment, incomplete outcome data, and selective reporting) compared with those published before 1990.

Is it necessary to search more than Medline in a methodologically rigorous systematic review? The Cochrane Collaboration is known for using higher quality methods than non-Cochrane reviews [4] and the Cochrane Handbook recommends searching at least two electronic databases when conducting a systematic review [5]. However, Halladay and colleagues found that searching beyond PubMed did not contribute substantially more information to meta-analysis estimates[8812]. The researchers selected a random sample of 50 Cochrane reviews and determined whether the 2,700 included studies were indexed in PubMed and/or EMBASE. They found that excluding the citations only identified in EMBASE did not bias meta-analysis estimates.

The immense amount of funding of patient reported outcomes (or PROs) projects, such as the Patient Reported Outcomes Measurement Information System (PROMIS), funded by the National Institutes of Health [6] and Patient-Centered Outcomes Research Institute (PCORI) funded by the United States Congress [7] need to be used not only for research but also for direct patient care. Kroenke and colleagues propose an interesting set of eight criteria for facilitating the incorporation of patient reported outcomes into clinical practice[8865]. Their framework consists of determining whether the scores can be used to act, considering the relevance of the clinical setting, comprehensiveness of the measure, reliability and validity of self-administration, brevity and simplicity of the included items, options for responses (e.g., number of options per item, duration of time for recall), scoring simplicity and interpretability, and accessibility of the measure (e.g., within the public domain, available in multiple languages). The authors reviewed a number of scales for these characteristics and showed that few met these criteria. The Journal was in correspondence with the authors because they did not include scales for which the
questionnaire scoring method was publicly available. However, because of this decision, the short-form (SF)-36 was excluded, which is one of most frequently referenced PRO scales in the world. This raises the issue of the legitimacy of scales that do not make their scoring method freely available. In the era of increased transparency, perhaps journals should consider focusing publication on manuscripts that provide PRO questionnaires with items that are publicly available, along with their scoring method. This is something that the Journal is currently debating.

Finally, Birring and colleagues developed a health status questionnaire for patients with interstitial lung disease[8860]. Factor analysis (or impact factor methods as per the authors) was used in order to develop the questionnaire, which is when items are selected according to the frequency and importance to patients [8]. For generating health status questionnaires, factor analysis has mostly been replaced by Rasch analysis. A Rasch analysis is a more complicated analysis based on the probability that a person with a given ability level will answer correctly and treats the difficulty of each item as information to be incorporated in scaling items. The Rasch analysis is appealing because it can be used to shorten the number of items on a questionnaire. The authors compared their results from the factor analysis with another version that was developed using Rasch analysis. The authors found that both the factor analysis and the Rasch analysis resulted in valid measures of health status that produced comparable results.

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