

defined *a priori* (*post-hoc* analysis). Thirty-two percent of studies did not leave explicit in the conclusion it was an exploratory analysis and the success rate of positivation was 91% (95% CI = 80% - 97%).

**Conclusions** Subsequent publication of subanalysis from originally negative trials is frequent, commonly not defined *a priori*, commonly not explicit about the exploratory nature and highly successful in positivating results. This suggests lack of ecosystem scientific integrity.

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### APPLYING A THRESHOLD CONTROLLED TRIAL IN ORDER TO ASSESS THE EXTERNAL VALIDITY OF RANDOMIZED CONTROLLED TRIALS AND TO OPTIMIZE THE SELECTION OF PATIENTS FOR TREATMENT TO MAKE EVIDENCE MORE RELEVANT

Huw Llewelyn. *Aberystwyth University, Aberystwyth, UK*

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**Objectives** Randomized controlled trials (RCTs) are the 'gold standard' method used to assess the efficacy of treatments. However, patients may be reluctant to be subjected to another RCT once efficacy has been firmly established, e.g. in order to examine the effect on efficacy of using a different selection criterion for treatment. A different approach to RCTs would help in such a situation. Regression discontinuity is one way of doing this in order to assess the external validity of a RCT but it cannot be used also to assess the effect of changing treatment selection criteria. A method will be described here that allows the result of a RCT to be predicted based on the assumption of constant odds ratio after patients above and below a threshold are offered different interventions.

**Method** Subjects are allocated to a control limb if the results of the test used to select them for the trial are on one side of some threshold and allocating them to a treatment limb if the results are on the other side of the threshold. The results are interpreted by assuming that the distribution of pre-treatment test results in those with a subsequent outcome is the same for those in the treatment and placebo limbs. This is the assumption made when using relative risk and odds ratios to apply the result of an RCT to patients with different baseline risks. This approach is illustrated with a data set from a RCT where the diagnostic test was the albumin excretion rate, the treatment was an angiotensin receptor blocker and the outcome was biochemical nephropathy. The result of the full RCT is compared with the result of a 'threshold controlled trial'.

**Results** When curves are constructed to show the probabilities of an outcome (nephropathy) on placebo and treatment for each diagnostic test result by using all the data from the RCT and from only the part of the data that would have been available from a threshold trial, the results were very similar, the small differences being readily explicable due to minor stochastic variation. In particular, the distribution of pre-treatment AER in those with and without subsequent nephropathy was the same in the treatment and placebo limbs. The proportion estimated to respond to the RCT in the threshold study was the same as in the full RCT. Also, the AER threshold when treatment began to be effective was similar in the threshold study and in the RCT. The results are described in a preprint.<sup>1</sup>

**Conclusions** Provided that suitable controls are in place, (e.g. double blinding) it appears that a threshold study can predict the result of a RCT. This is invaluable as it promises to allow studies to be performed to compare interventions when randomisation is not possible. It would allow the external validity of a RCT result to be assessed during day to day care. It would also allow new diagnostic tests to be assessed in order to see how well they can select patients for treatment in order to avoid over-treatment.

### REFERENCE

1. Llewelyn H. *Estimating the result of randomised controlled trials without randomisation in order to assess the ability of diagnostic tests to predict a treatment outcome*. 2018. <http://arxiv.org/abs/1808.09169>

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### (IN)CONSISTENCY OF RECOMMENDATIONS FOR EVALUATION AND MANAGEMENT OF HYPERTENSION

<sup>1,2</sup>Martin Mayer, <sup>1,3</sup>Brian Alper, <sup>4,5</sup>Amy Price, <sup>6</sup>Esther van Zuuren, <sup>7</sup>Zbys Fedorowicz, <sup>8</sup>Allen Shaughnessy, <sup>1</sup>Peter Oettgen, <sup>9</sup>Glyn Elwyn, <sup>10</sup>Amir Qaseem, <sup>11</sup>Ilkka Kunnamo, <sup>4</sup>Urvi Gupta, <sup>12</sup>Deborah Carter, <sup>13</sup>Michael Mittelman, <sup>14</sup>Carla Berg-Nelson. <sup>1</sup>EBSCO Health, Ipswich, MA, USA; <sup>2</sup>Cone Health, Greensboro, NC, USA; <sup>3</sup>University of Missouri-Columbia School of Medicine, Columbia, MO, USA; <sup>4</sup>Stanford Medicine X, Stanford, CA, USA; <sup>5</sup>University of Oxford, Oxford, UK; <sup>6</sup>Leiden University Medical Centre, Leiden, Netherlands; <sup>7</sup>Veritas Health Sciences Consultancy, London, UK; <sup>8</sup>Tufts University School of Medicine, Medford, MA, USA; <sup>9</sup>The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, NH, USA; <sup>10</sup>American College of Physicians, Philadelphia, PA, USA; <sup>11</sup>Duodecim, Helsinki, Finland; <sup>12</sup>Murdy Consultant Group, Newark, OH, USA; <sup>13</sup>American Living Organ Donor Fund, Philadelphia, PA, USA; <sup>14</sup>Society for Participatory Medicine, Nutting Lake, MA, USA

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**Objectives** To systematically assess the consistency of recommendations regarding hypertension management across clinical practice guidelines (CPGs) and electronic point-of-care (POC) resources

**Method** We identified hypertension management recommendations from eight CPGs and two POC resources in April 2018. We described discrete and unambiguous specifications of the population, intervention, and comparison states to define a series of reference recommendations. Three raters reached consensus on coding the direction and strength of each related recommendation made by each CPG and POC resource.

For each reference recommendation, we analyzed the rate of consistency for direction and strength. We did this for the eight CPGs and for the group of ten recommendation sources. We also conducted sensitivity analyses testing the robustness of our findings to the exclusion of recommendation statements of 'insufficient evidence' and to the exclusion of single recommendation sources. We also assessed the CPG and POC resources for evidence of public and patient involvement, patient-facing information, and shared decision-making tools, and we involved patient and public representatives in this assessment.

**Results** Considering all 10 recommendation sources, 12 of 71 recommendations (16.9%) were consistent in direction and strength, 21 (29.6%) consistent in direction but inconsistent in strength, and 38 (53.5%) inconsistent in direction. Considering only the CPGs, 25 recommendations (35.2%) were consistent in direction and strength, 13 (18.3%) consistent in direction but inconsistent in strength, and 33 (46.5%) inconsistent in direction. Excluding 'insufficient evidence' ratings did not explain the inconsistency, and a leave-one-out sensitivity

analysis suggested the inconsistency is not due to any single recommendation source. These findings held whether considering all recommendation sources or only CPGs. One recommendation source reported patient or public involvement. Six included very general information about how to include patients in individual decision-making, and three provided direct-to-patient guidance. Two made tools available to help patients participate in individual decision-making, one suggesting an existing tool, and the other integrating the tool within the POC recommendation.

**Conclusions** Hypertension is a common chronic condition with widespread expectations surrounding guideline-based care, but CPGs have high degrees of inconsistency. Further investigation should determine the reasons for inconsistency, the implications for recommendation development, and the role of synthesis across recommendations for optimal guidance of clinical care.

Consideration of a patient's values and preferences is a fundamental part of practicing evidence-based medicine. Therefore, public and patient involvement is encouraged in CPG development just as shared decision-making is encouraged in clinical practice. With a substantial proportion of hypertension management guidance being weak or inconsistent, shared decision-making could replace algorithmic instructions as a primary framework for an approach to healthcare, but this will require development of patient decision aids and workflow support tools to make it practical.

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#### OPEN ACCESS BUDGET TOOLS FOR THE PLANNING OF RANDOMISED CONTROLLED TRIALS: A SCOPING REVIEW

<sup>1,2</sup>Benjamin Speich, <sup>2</sup>Viktoria Gloy, <sup>3</sup>Nadine Schur, <sup>2</sup>Lars G Hemkens, <sup>3</sup>Matthias Schwenklen, <sup>2</sup>Matthias Briel. <sup>1</sup>Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK, Oxford, UK; <sup>2</sup>Basel Institute for Clinical Epidemiology and Biostatistics, Department of Clinical Research, University of Basel and University Hospital Basel, Switzerland, Basel, Switzerland; <sup>3</sup>Institute of Pharmaceutical Medicine, University of Basel, Basel, Switzerland, Basel, Switzerland

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**Objectives** Well conducted randomised controlled trials (RCTs) generate the most trustworthy evidence when newly developed or already existing clinical interventions are evaluated. However, RCTs require substantial resources and the costs seem to be increasing over time. As a result, the number of independent investigator-initiated RCTs decreased and a considerable proportion of RCTs are prematurely discontinued due to recruitment delays. Especially in academic research, it is common that clinical studies are underfinanced or that the compensations paid by funders or industries do not cover the actual costs. Therefore, tools for investigators to plan their budgets accurately are essential for the successful conduct of an RCT. In this scoping review we aimed to give an overview of the publicly available budget planning tools.

**Method** We systematically searched Medline, EMBASE (both via Ovid) and EconLit from inception until May 2018. Additionally, two reviewers conducted an internet search between June and October 2018. We included any tools or cost templates and categorised them if they were primarily intended to (i) plan a budget for an entire RCT, (ii) plan a budget for a separate centre participating in a RCT, or (iii) monitor costs during the conduct of an RCT. From all tools we assessed if

they considered direct costs (fixed costs and variable costs) as well as indirect costs, and if they were user tested or validated in any form.

**Results** We identified 25 tools which were included (i.e. two from the literature search and 23 from the internet search). Of those, 22 tools consisted of programmed Microsoft excel sheets. Seven tools were developed to plan the budget for an entire RCT, 17 tools helped to calculate budgets for a separate study centre participating in an RCT, and the purpose of one tool was to monitor ongoing costs of RCTs. Direct costs, consisting of fixed costs and variable costs were considered by 25 and 21 tools, respectively. Indirect costs were considered by 19 tools. Overall, 18 tools considered all three of these cost aspects. Of the seven tools which can be used to plan costs of an entire RCT, only two included all three relevant cost aspects. Overall, we identified a description of user testing or validation for two tools only.

**Conclusions** A variety of freely accessible budget planning tools for RCTs exist. Most of the tools were developed internally by different institutions and were not published in a scientific journal. Often it remained unclear if they underwent any form of validation or if they can also be applied in a useful way by researchers who are not part of the institution which developed the tool. We did not find any evidence during this project that a single tool was broadly applied for planning RCT budgets. The fact that many different organisations put effort in developing a budgeting tool shows that the need for accurate planning of RCT budgets was recognised at many levels. Identifying or creating a user-friendly tool which can be used flexibly for different RCTs in different settings should therefore be a research priority.

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#### LONGITUDINAL CURRICULUM FOR CERTIFIED TRAINING IN EVIDENCE-BASED MEDICINE: CERTIFIED EVIDENCE-BASED MEDICINE PRACTITIONER. (CEBMP)

<sup>1</sup>Izhar Hasan, <sup>2</sup>Uzair Hasan, <sup>3</sup>Salman Habib Abbasi, <sup>4</sup>Shankar Srinivasan, <sup>5</sup>Babar Rao. <sup>1</sup>MDACCESS, Princeton, USA; <sup>2</sup>MDACCESS, Princeton, NJ, USA; <sup>3</sup>Hi Tech Medical college, Taxilla, Pakistan; <sup>4</sup>Department of Health informatics, Rutgers university, Newark, NJ, USA; <sup>5</sup>Robert wood Jhonson Medical school, Somerset, New Jersey, USA

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**Objectives** Training in evidence based medicine practice is a mandatory core competency of practice based learning and improvement (PBLI) of ACGME standards. Reflective medical education is a triggering point for self-directed learning at the point of care in wards, clinics and in operating rooms to capture patient specific clinical queries. Both these skills can be taught through a longitudinal curriculum which emphasizes on patient and learner-centered education. However, there is no formal longitudinal curriculum to teach reflective learning and evidence-based medicine to medical students and trainees in a clinically integrated learning environment during multiyear training. Web based certification training is a growing trend to demonstrate commitment to professionalism, and offers a formal training to meet the standards for self-directed learning for professional development

**Method** Our objective is to implement a web based longitudinal curriculum for certified training in evidence-based medicine. We plan to customized specialty based longitudinal training in evidence based medicine practicing skills. Furthermore, our goal is to identify the areas of insufficient or poor evidence in each specialty to emphasize the training in skills