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.

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

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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.

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

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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

in appraising and interpreting evidence type in the hierarchy of evidence-based medicine resource's pyramid. EBM curriculum will include longitudinal training both in inpatient and outpatient setting to capture all relevant point of care patient centered clinical queries mapped to specialty topics of insufficient evidence. A built-in knowledge resource, multi modal teaching methods including small group teaching, e- learning and journal club will ensure a comprehensive training in EBM. The ultimate outcome will be a certified training in evidence-based medicine at the conclusion of the residency training for life long evidence-based practice.

Results We have implemented a web-based EBM curriculum platform hosted at *www.ebmcentral.net*. Preliminary testing at various workshops have been conducted with positive feedback. Beta study results showed that web based longitudinal curriculum provides an excellent opportunity to train students, resident and faculty in practicing evidence-based medicine through a formal longitudinal EBM curriculum. A clinically integrated curriculum along with innovative EBM tools provides a simulated article reading and appraisal training. A point of care query capturing tool and meta search engine for EBM resources provides a convenient platform to trigger self-directed point of care learning for EBM cycle. Self-directed web-based assignments along with both summative and formative assessment ensure a continuous growth of required competencies in longitudinal curriculum timeline. Lastly, research dissemination through a collaborative crowd research environment to synthesize research evidence such as systematic review is also integrated.

Conclusions We have conceived and implemented a web based longitudinal curriculum for a certified training in evidence-based medicine i**.e Certified evidence-based medicine practitioner (CEBMP).** Our platform has provided preliminary supportive evidence of enhancing reflective learning, knowledge gaps and needs assessment, and clinically integrated formal training in evidence-based medicine. A personal knowledge repository along with acquired skills of evidence-based medicine including question formulation, information mastery, critical appraisal, research synthesis and interpretation provides a foundation for lifelong self-directed learning for evidence-based practice. We plan to conduct a randomized clinical trial to assess the role of our longitudinal curriculum in providing certified training in evidence-based medicine to medical students, residents and faculty.

34 PATIENT AND PUBLIC INVOLVEMENT IN RESEARCH AGENDA-SETTING AND CLINICAL TRIALS: WHY, WHEN AND HOW

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Objectives The research agenda in medicines development has traditionally been established without input from its beneficiaries i.e. patients. However, patient and public involvement (PPI) is increasingly being recognised as important in medicines development, to ensure more meaningful medicines development by the pharmaceutical industry and generate new insights to aid regulatory review and decision-making. Besides, involving the public in any decision that affects their health is ethical, helps create a culture of transparency, and improves acceptance of decisions. The increased relevance to patients may subsequently lead to improved recruitment and retention in clinical trials, another key stage in the medicine's development lifecycle. Other benefits of PPI in clinical trials include reduced numbers of protocol amendments and better accessibility of resulting evidence to the public. Given the lack of guidance on PPI in research agenda-setting and clinical trials, we aimed to develop practical evidence-based guidance on the role of PPI in these areas.

Method Development of the PPI guidance involved three main tasks. First, was a critical review of existing literature and resources to collate material related to PPI in research agenda-setting and clinical trials. The next task involved an iterative process, working collaboratively with the PPI Panel for Antimicrobial Drugs (PPIPAD), comprising individuals who had experienced an acute infection requiring admission into an intensive-care unit, either personally or as a carer. At each PPIPAD meeting, members were presented with a draft version of the guidance, and asked to comment on aspects such as language, layout and content. Researchers carefully considered these contributions and revised the guidance accordingly. This process was repeated until a final version was produced and agreed. Lastly, this co-produced guidance was piloted at a workshop for project managers and officers at the Julius Centre, University Medical Centre Utrecht, renowned for its applied clinical research and innovations in clinical research methodology.

Results The guidance presents evidence for the role of PPI, including practical 'how-tos' and real-world examples. It describes two approaches to PPI in research agenda-setting: the Dialogue Model, and the James Lind Alliance Priority Setting Partnerships. In clinical trials, patients (different from patients participating in a trial) can be involved in trial design and protocol development by advising on the relevance of patient-reported outcomes and outcome measures, improving access to and recruitment of participants, and assisting in the development of patient-related materials (informed consent documents, data collection tools). In trial conduct, patients have a role in supporting operations and clinical infrastructure, advising on any trial adaptations, and ensuring accountability of researchers. The role of PPI in trial data analysis and dissemination of results includes ensuring coherence in the understanding and interpretation of data, contributing to the analysis of participant feedback on trial experiences, and assisting in the development of patient-level communication.

Conclusions There is potential to incorporate PPI from an early stage in the medicines development lifecycle i.e. setting the research agenda, and across all stages of the clinical trial continuum. In addition to the benefits of PPI, we acknowledge the challenges associated with it. Successful implementation of PPI in these areas requires clear goals and well-developed plans for responsive and managerial PPI roles, equal partnership between stakeholders and patients, and the provision of ongoing information and education to empower and facilitate the active involvement of patients.

This guidance for PPI in research agenda-setting and clinical trials has been included as two individual chapters in the PPI Toolkit and Practical Guide for Antimicrobial Medicines Development Research, developed for COMBACTE-MAGNET's clinical coordinating work package. COMBACTE-MAGNET (Combatting Bacterial Resistance in Europe – Molecules against Gram-Negative Infections) is a consortium of academic and industry researchers committed to seeking new ways to treat multi-resistant bacterial infections.