Discussion Even though the focus group procedures varied, there was significant overlap and repetition in the feedback received on the same guideline resources. The patient focus group facilitated by a clinician engaged participants in discussions oriented to clinical issues. The comic book was considered to be a novel communication vehicle by clinicians but not so by public.

Implications for Guideline Developers/Users Involving a motivated Lay Committee facilitated by someone not directly related to the project seems to be a valuable alternative to other focus groups of patients which may require more effort and resources.

MEDICAL PRACTICE AND CLINICAL EFFECTIVENESS

IMPLEMENTING NUTRITION GUIDELINES THROUGH USE OF NON-RANDOMISED STUDIES IN THE GUIDELINE TRANSFORMING EVIDENCE FROM MULTIPLE

Methods Mixed methods descriptive study guided by CAN-IMPLEMENT©. The process involved: a) conducting a systematic search for guidelines; b) developing symptom-specific protocols using evidence from quality appraised clinical practice guidelines; c) reaching consensus on the clinical practice protocol template, and d) validating the clinical practice protocols.

Results Clinical practice protocols were developed and validated for 13 symptoms using 42 clinical practice guidelines with a median of 3 guidelines per protocol (range 1 for bleeding to 7 vomiting). For the first two protocols, source guideline AGREE rigour subscale ratings ranged from 8% to 86% (median 60.1; diarrhoea; 40.5 fever). The protocols were developed using guidelines, symptom severity questions included the Edmonton Symptom Assessment System, and iterative feedback from practicing nurses. Usability testing revealed: high readability, just the right amount of information, and appropriate terms. Access to protocols needs to be tailored to individual practices (e.g. electronic application, access to paper-based versions). Nurses requested training and support to implement them.

Discussion These tools, created from guidelines, transform evidence into user-friendly protocols for use by nurses when guiding patients at home to better manage their cancer treatment-related symptoms.

USE OF NON-RANDOMISED STUDIES IN THE GUIDELINE PROCESS: THE GRADE APPROACH

Background The GRADE approach to guideline development requires a review of the best available evidence which includes randomised controlled trials (RCTs) and non-randomised studies (NRS).

Objectives Describe the use of NRS as a replacement, a sequence, or a complement for RCTs, in a World Health Organization guideline using the GRADE approach.

Methods We searched the literature using no study type limits for the effect of screening and treatment of precancerous lesions on patient or population important outcomes and for baseline risks. We assessed quality of the evidence using GRADE.

Results Depending on the outcomes, we found few to no RCTs. When there was low/very low overall quality evidence from RCTs, we used NRS studies with no independent control groups to compare proportions between groups and calculate a relative effect of treatment and this evidence replaced the RCT evidence with similar/higher quality evidence. We found no evidence in RCTs for long-term outcomes, such as spontaneous abortion. Therefore, we used data from NRS (cohort studies) for premature delivery (a surrogate) to provide sequential evidence. For evidence about baseline risk of precancerous lesions and other outcomes, we used NRS a complement to the RCT data.

Discussion Data from NRS provided evidence in three ways. One key criterion to consider when grading this evidence is indirectness due to indirect comparisons, surrogate outcomes or varying population risks.
Abstracts

056 ADDRESSING CONTINUOUS DATA FOR PARTICIPANTS EXCLUDED FROM TRIAL ANALYSIS: A GUIDE

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Background Guideline developers addressing quality of evidence commonly confront studies with missing data.

Objectives To develop a framework for assessing risk of bias resulting from missing participant data for continuous outcomes in systematic reviews.

Methods We developed a range of progressively more stringent imputation strategies to challenge the robustness of the pooled estimates. We applied our approach to two systematic reviews.

Results We used 5 sources of data for imputing means for participants with missing data: [A] the best mean score among the intervention arms of included trials, [B] the best mean score among the control arms of included trials, [C] the mean score from the control arm of the same trial, [D] the worst mean score among the intervention arms of included trials, [E] the worst mean score among the control arms of included trials. Using these sources of data, we developed four progressively more stringent imputation strategies. In the first example review, effect estimates were diminished and lost significance as the strategies became more stringent, suggesting the need to rate down confidence in estimates of effect for risk of bias. In the second review, effect estimates maintained statistical significance using even the most stringent strategy, suggesting missing data does not undermine confidence in the results.

Discussion Our approach provides rigorous yet reasonable and relatively simple, quantitative guidance that guideline developers can use for judging the impact of risk of bias as a result of missing participant data in systematic reviews of continuous outcomes.

057 HANDLING TRIAL PARTICIPANTS WITH MISSING DATA IN META-ANALYSES OF DICHOTOMOUS OUTCOMES: GUIDANCE FOR SYSTEMATIC REVIEWERS

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Background Systematic reviewers including all randomised participants in their meta-analyses need to make assumptions about the outcomes of those with missing data.

Objectives To provide systematic review authors with guidance on dealing with participants with missing data for dichotomous outcomes.

Methods The authors used an iterative process of suggesting guidance and obtaining feedback to arrive at a proposed approach.

Results For participants with missing data, systematic reviewers can use a range of plausible assumptions in the intervention and control arms. Extreme assumptions include ‘all’ or ‘none’ of the participants had an event, but these assumptions are not plausible. Less extreme assumptions may draw on the incidence rates within the trial (e.g., same incidence in the trial control arm) or in all trials included in the meta-analysis (e.g., highest incidence among control arms of all included trials). The primary meta-analysis may use either a complete case analysis or a plausible assumption. Sensitivity meta-analyses to test the robustness of the primary meta-analysis results should include extreme plausible assumptions. When the meta-analysis results are robust to extreme plausible assumptions, inferences are strengthened. Vulnerability to extreme plausible assumptions suggests rating down confidence in estimates of effect for risk of bias.

Conclusions This guidance proposes an approach to establishing confidence in estimates of effect when systematic reviewers are faced with missing participant data for binary dichotomous outcomes in randomised trials.

058 ASSESSMENT OF THE EVIDENCE FOR DIAGNOSTIC TESTS AND STRATEGIES: A SYSTEMATIC REVIEW OF AVAILABLE TOOLS

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Background The challenges facing guideline developers when making recommendations about diagnostic tests and strategies (DTS) are considerably different when compared to treatment recommendations.

Objectives To identify, describe and compare all available instruments, checklists, critical appraisal tools, and indices designed for assessing the quality of evidence (QoE) or strength of recommendations (SoR) dealing with diagnostic tests and strategies.

Methods We conducted a comprehensive systematic search of the literature including state of the art diagnostic guidelines, recommendations, checklists, critical appraisal tools, and indices designed papers and diagnostic systematic reviews.

Results We identified 43 tools and modifications of existing tools to assess the QoE and SoR of DTS. Most tools acknowledge the importance of assessing the QoE and SoR separately. Most tools include individual quality criteria and study design but no tools rates all quality criteria suggested by the GRADE working group. Only two tools explicitly consider factors that increase the confidence in the evidence. When moving from evidence to recommendations, patient values and preferences and resources were rarely considered.

Discussion There is confusion about the terminology that describes the various factors that influence the QoE and SoR. The criteria for evaluating the QoE and moving from evidence to recommendations are incomplete for most guideline development frameworks that we evaluated.

Implications for Guideline Developers/Users The GRADE approach is the most complete approach encompassing all factors but users will benefit from a better description of the