evidence to recommendation framework in GRADE and clarification of issues that relate to laboratory validity parameters.

## 059 NONRANDOMISED STUDIES AS A SOURCE OF COMPLEMENTARY, SEQUENTIAL OR REPLACEMENT EVIDENCE FOR RANDOMISED CONTROLLED TRIALS IN SYSTEMATIC REVIEWS AND GUIDELINES

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**Background** The terms applicability, generalizability, external validity, transferability generally describe one overarching theme: can available research evidence be utilised to answer the health care questions at hand, ideally supported by a judgement about the degree of confidence in this utilisation. This concept has been called directness.
**Objectives** To offer conceptual and practical guidance to those judging directness and using research evidence from non-randomised studies (NRS).
**Methods** We used a literature review and feedback from participants of a workshop funded by the Agency for Healthcare Quality and Research and the Cochrane Collaboration.
**Results** Guideline developers can use NRS as a source of complementary, sequential or replacement evidence for randomised controlled trials (RCTs) by focusing on judgements about the population, intervention, comparison and outcomes. They use NRS to complement judgements about inconsistency, the rationale and credibility of subgroup analysis, baseline risk estimates for the determination of absolute benefits and downsides, and the directness of surrogate outcomes. Authors use NRS as sequential evidence to provide evidence when the evidence from RCTs is insufficient (e.g. long-term harms). Use of evidence from NRS may also replace RCT evidence when RCTs provide indirect evidence but NRS provide overall higher quality, direct evidence. We developed a simple tool and algorithm to make judgements about indirectness more transparent.
**Discussions** These judgements need to be made in the context of other quality of evidence domains.
**Implications for Guideline Developers/Users** The transparency of the framework will support interaction with those making health care decision and policy.

## 060 APPRAISING IMPLEMENTABILITY DURING THE DEVELOPMENT PROCESS RESULTED IN GUIDELINE REVISION

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**Background** The GuideLine Implementability Appraisal (GLIA) instrument has been suggested for identifying potentially remediable implementability issues during the guideline development process.
**Objective** To explore to what extent using GLIA during the development process would result in guideline revision before publication.
**Methods** The development process of the European hyponatremia guideline -coordinated by European Renal Best Practice - was our study context. Using the GLIA web-tool, eleven clinicians and methodologists from eight countries individually appraised 27 guideline statements. In a face-to-face consensus meeting, four GLIA panelists and one guideline development group (GDG) representative summarised potential implementability issues. The GDG discussed these issues, and revised the guideline if deemed necessary.
**Results** We identified 33 issues; the GDG accepted 26 as potentially hampering implementability. This resulted in statement reformulation with (n=5) and without (n=10) influencing clinical content, adding or (re)moving entire statements (n=8), and adding information to tables or rationales (n=3). The majority of issues declined by the GDG (n=7) addressed clinical situations that were covered elsewhere in the guideline or were considered to be uncommon.
**Discussion** Using GLIA during the development process resulted in a revised guideline. We felt that GDG representation in the consensus meeting optimize our appraisal process.
**Implications for Guideline Developers/Users** Guideline organizations may want to consider incorporating GLIA into their development process. This may raise GDGs' awareness of potential implementability issues, and allow revision of the guideline accordingly prior to publication. Future research should explore the effect of GLIA-based revisions on implementability as assessed by guideline users.

## 061 GUIDELINE IMPLEMENTABILITY APPRAISAL (GLIA) IN US NATIONAL GUIDELINES

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**Background** Guidelines must be implemented in order to impact health outcomes. Identifying and addressing potential barriers to implementation during guideline development can improve implementability.
**Objectives** To describe the processes and results of embedding guideline implementability appraisal, into prominent US cardiovascular disease risk reduction guidelines.
**Methods** The GuideLine Implementability Appraisal (GLIA) tool (Yale Center for Medical Informatics), was integrated into the guideline development processes of a US national-level organisation. A member of the Implementation Science Work Group (ISWG) with prior experience in GLIA appraisals trained the Guideline Development Teams (GDTs), early in the guideline development process, with the intent of raising awareness of potential barriers to implementation so they might be addressed during guideline development. Formal GLIA appraisals were performed on the drafts of the guideline reports, by members of the ISWG, as well as volunteers from outside the guideline programme. To minimise interference with timelines, appraisals were carried out and written reports returned to the GDTs within 2 weeks of release of the draft reports.
**Results** A number of potential barriers to implementation were identified in the draft reports, such as: use of inexplicit terms in recommendation language, inconsistency of thresholds and terms used within a guideline, unclear applicability of assessment