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## Original Research

# Innovative tools for quality assessment: integrated quality criteria for review of multiple study designs (IGROMS)<sup>☆</sup>

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## ABSTRACT

**Objectives:** With the aim to facilitate a more comprehensive review process in public health including patient safety, we established a tool that we have termed IGROMS (Integrated quality Criteria for the Review Of Multiple Study designs), which unifies, integrates and refines current quality criteria for a large range of study designs including qualitative research.

**Study design:** Review, pilot testing and expert consensus.

**Methods:** The tool is the result of an iterative four phase process over two years: 1) gathering of established criteria for assessing controlled, non-controlled and qualitative study designs; 2) pilot testing of a first version in two systematic reviews on behavioural change in infection prevention and control and in antibiotic prescribing; 3) further refinement and adding of additional study designs in the context of the European Centre for Disease Prevention and Control funded project 'Systematic review and evidence-based guidance on organisation of hospital infection control programmes' (SIGHT); 4) scrutiny by the pan-European expert panel of the SIGHT project, which had the objective of ensuring robustness of the systematic review.

**Results:** IGROMS includes established quality criteria for randomised studies, controlled before-and-after studies and interrupted time series, and incorporates criteria for non-controlled before-and-after studies, cohort studies and qualitative studies. The tool consists of two parts: 1) a list of quality criteria specific for each study design, as well as criteria applicable across all study designs by using a scoring system; 2) a 'decision matrix', which specifies the robustness of the study by identifying minimum requirements according to the study type and the relevance of the study to the review question. The decision matrix directly determines inclusion or exclusion of a study in the review. IGROMS was applied to a series of systematic reviews to test its feasibility and usefulness in the appraisal of

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multiple study designs. The tool was applicable across a wide range of study designs and outcome measures.

**Conclusion:** ICROMS is a comprehensive yet feasible appraisal of a large range of study designs to be included in systematic reviews addressing behaviour change studies in patient safety and public health. The tool is sufficiently flexible to be applied to a variety of other domains in health-related research. Beyond its application to systematic reviews, we envisage that ICROMS can have a positive effect on researchers to be more rigorous in their study design and more diligent in their reporting.

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## Introduction

Systematic reviews have become the cornerstone of evidence-based medicine. Most of them focus on randomized controlled trials (RCTs) to collate empirical evidence to inform best practice<sup>1</sup> because this study design is considered the best for establishing evidence-base for medical treatments. Behaviour change interventions are often considered unsuitable to be tested by randomised controlled trials and the UK Medical Research Council called to consider randomised study designs also for complex interventions.<sup>2</sup> However, randomised study designs are still rare in patient safety and public health, and experts in the field expressed the need to broaden the knowledge base in areas such as social sciences, translational research, professional practice issues, and organisational, financial and regulatory systems.<sup>3,4</sup> Due to the variation of study designs in the area of patient safety and public health meta-analyses are often not feasible, although a variety of methodological approaches are becoming available for reviewing evidence, ranging from more traditional systematic reviews to realist reviews and meta-narrative syntheses.<sup>5,6</sup> Interpretive methods for evidence synthesis have also emerged as viable alternatives to more conventional aggregative reviews.<sup>4,7,8</sup> The body of literature is constantly rising in the field of patient safety and public health and there is an increasing need to critically appraise a broader range of study designs in reviews in order to support decision-making about e.g. the (cost-) effectiveness and the mechanisms of action in complex behaviour change interventions.<sup>8</sup> Even within the systematic review paradigm, it has been acknowledged that study designs other than RCTs can add significant value to the evidence-base of quantitative research by allowing a more inclusive evaluation of interventions that contain many independent and inter-dependent variables and provide local contexts on efficacy.<sup>3</sup> The Cochrane Effective Practice and Organisation of Care Review (EPOC) group promoted the inclusion of quasi-experimental research designs in reviews such as interrupted-time-series (ITS) and controlled before-and-after (CBA) studies but advised against including non-controlled studies.<sup>9</sup>

Systematic reviews in dynamic environments with numerous social, cultural and contextual influences are limited to provide the full range of information about the evidence of behavioural interventions if including RCTs and ITS studies only.<sup>10</sup> This is mainly due to the fact that behavioural

interventions as such (change of behaviour, change of practice at the patient) are less tangible, can be less controlled, and depend largely on the socio-cultural context.<sup>10,11</sup> Controlled studies such as CBA or controlled ITS offer a better estimate of the effect and their contribution to the evidence base is less debated.<sup>9</sup> Non-controlled studies such as non-controlled before-after (NCBA), cohort studies or ITS are limited in providing evidence due to potential bias but still can offer useful information about the efficacy of an intervention aiming at improving patient safety if performed correctly and mitigating the lack of control. Exclusion of such designs from reviews results in a significant number of information being missed from the evidence-base.<sup>12,13</sup> Even more rarely do systematic reviews assess qualitative literature to gain a more in-depth understanding of how contextual factors influence efficacy.<sup>10</sup> Qualitative studies do not provide estimates of an intervention but they are valuable in determining individual, organisational, social, cultural and environmental influences on practice and processes and in providing insights into participants' perceptions, reasons for adopting (or not adopting) certain behaviours, as well as transferability of best practice across contexts.<sup>14</sup> Reviews incorporating qualitative studies show that they can provide evidence for contextual efficacy and effectiveness.<sup>15,16</sup> Qualitative studies do complement quantitative results, which, on the other hand, add statistical association or causation.<sup>17</sup> There is little debate about the benefit of looking at both quantitative and qualitative studies when assessing the effectiveness of behavioural interventions in public health or IPC.

We take the view that reviews should consider all methodologically robust and relevant studies, including NCBA, cohort studies, and qualitative studies so that these methods can contribute to the evidence-base in patient safety and public health and directly inform clinical practice and policy making. We are conscious about the limitations of such study designs, including for example difficulties in determining the difference between secular trends and the effect of an intervention on behaviour change, in evaluating the impact of confounding variables in NCBAs.<sup>18–20</sup> However, transparency in reporting factors that may influence outcome<sup>18</sup> or in relation to researcher bias, reflexivity and reliability of data, can result in meaningful evidence from NCBA, cohort and qualitative studies.

The consideration of a greater variety of study designs for inclusion in reviews is a challenge because different quality criteria must be appraised for the distinct study

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