

Reporting guidelines for operational / implementation research:

29 October

Title and abstract	Identify as implementation or operational research in the title Provide a structured summary of study context, rationale, objectives, design, methods, results and conclusions.
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Introduction	
Background	Explain the scientific background relating to both the intervention and the implementation. What is already known about the issue? Describe the policy or programme context. Describe relevant elements of setting or settings (for example, geography, physical resources, organisational culture, history of change efforts). What is it about implementation in this setting that warrants research and reporting of findings?
Problem	Briefly describe the nature and severity of the specific issue or problem that was addressed. Specify who (champions/supporters) what (events/observations) triggered the decision to make changes, why in this location and why now?
Intervention	What evidence-based intervention or innovation is proposed?
Implementation theory	Describe mechanisms or strategies by which components were expected to cause changes, and plans for testing whether these were effective.
Intended improvement	Describe the specific aim of the proposed study (changes/improvements in processes and outcomes).

Methods	
Study design	Identify the study design (for example, observational, quasi-experimental, experimental, qualitative, mixed) chosen for measuring impact of the intervention on primary and secondary outcomes, (if relevant).
Setting	Exact details of study locations, baseline population characteristics, recruitment of participants, relevant dates for implementation, follow-up, and data collection
Implementation	Describe the intervention. The amount of detail given should be sufficient to allow replication of the study. For well-established interventions, it is sufficient to refer to previously published studies. Give a description of the implementation strategy: frequency, duration, intensity, including how and when interventions were actually implemented, additional resources required to support implementation, mode of delivery, why and when the study ended.

Explain methods used to assure data quality (for example, blinding; repeating measurements and data extraction; training in data collection; collection of sufficient baseline measurements).

Participants

For qualitative studies: what was the approach (eg. ethnography, grounded theory, narrative) and theory?

Indicate how size of target population was determined.

Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up

Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls

Cross-sectional study—Give the eligibility criteria, the sources and methods of selection of participants

For matched studies, give matching criteria and number of exposed and unexposed or the number of controls per case

For randomized studies, how was randomization done, definition of clusters for cluster randomized studies. Was the study blinded?

Variables

Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers.

Data sources/ measurement

For each variable of interest, give sources of data and methods of assessment (or measurement). Describe sampling strategies and comparability of assessment methods if there is more than one group.

Methods for processing data prior to and during analysis, including translation, transcription, data entry, data management and security, verification of data integrity, data coding, and deidentification.

Explain how variables were handled in the analyses. If applicable, describe which groupings were chosen and why; how data were coded.

Analyses

Which analyses were pre-specified, and which were exploratory?

For qualitative analyses: process by which inferences or themes were identified and developed, including the researchers involved in data analysis.

For quantitative analyses: describe statistical methods, including those used to adjust for sampling methods and control for confounding.

Where both qualitative and quantitative analyses are used, describe both types of analysis and how findings were synthesized.

Describe any methods used to examine subgroups and interactions.

Explain how missing data were addressed.

Cohort study: explain how loss to follow-up was addressed.

Case-control study: describe matching of cases and controls.

Ethical consideration	Including consent procedures, if relevant. How was confidentiality ensured? How was the balance between the potential risks and benefits of this research to individuals or communities assessed?
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Results

Descriptive data	Report numbers of individuals at each stage of study—eg. numbers eligible, included in the study, completing follow-up, and analysed. Include a flow diagram, timeline or graph, if relevant Cross tabulate the number of participants by subgroups as relevant eg. demographic, clinical, social characteristics, response rates, loss to follow up or other sources of missing data, potential confounders, for those who receive the intervention and those who do not receive it.
Outcomes	Explain the actual course of the intervention, if relevant. For example, describe the sequence of steps, events or phases; type and number of participants at key points, preferably using a time-line diagram or flow chart. Document the degree of success in implementation: <ul style="list-style-type: none"> • changes in processes and outcomes associated with the intervention. • changes observed in outcome (for example, population behaviour change, morbidity, mortality, function, patient/staff satisfaction, service utilization, cost, care disparities). • consider benefits, harms, costs, unexpected results, problems, failures.
Outcome data	Report numbers of outcome events (or summary measures over time), separately for those who receive the intervention and those who do not receive it. Include summary statistics and measure of variance (SD or SE).
Main results	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory. Provide unadjusted estimates of intervention effect, and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Consider translating estimates of relative risk into absolute risk for a meaningful time period. Synthesis of quantitative and qualitative results
Other analyses	Report other analyses done—eg analyses of subgroups and interactions, sensitivity analyses, costs.

Discussion

Key results	Summarise key results with reference to study objectives
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Limitations	<p>Discuss limitations of the study, taking into account possible sources of confounding, bias or imprecision in design, measurement, and analysis that might have affected study outcomes (internal validity).</p> <p>Discuss both direction and magnitude of any potential bias.</p>
Interpretation	<p>Interpret the results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.</p> <p>Compare and contrasts study results with relevant findings of others, drawing on broad review of the literature; use of a summary table may be helpful in building on existing evidence.</p> <p>Suggest steps that might be modified to improve future performance.</p> <p>Review issues of opportunity cost and actual financial cost of the intervention.</p>
Contextual factors	<p>Success factors, barriers and how they were overcome.</p>
Generalizability	<p>Discuss the generalizability (external validity) of the study results</p> <p>Explore factors that could affect generalizability – for example, representativeness of participants; effectiveness of implementation; dose-response effects; features of local setting.</p> <p>Applicability to other settings; Potential barriers to scale up</p>
Conclusion	<p>Consider overall practical usefulness of the intervention.</p> <p>Suggest implications for the implementation programme. How will the results be used/translated into practice in the context of the study?</p> <p>Suggest implications for further studies.</p>

Other information	<p>Indicate if the study is registered and if the data are available.</p> <p>Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.</p> <p>State the role of individuals in the study and any conflict of interest.</p>
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