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Standards for Reporting Implementation Studies (StaRI) statement

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Abstract

Implementation studies are often poorly reported and indexed, reducing their potential to inform initiatives to improve healthcare services. The Standards for Reporting Implementation Studies (StaRI) initiative aimed to develop guidelines for transparent and accurate reporting of implementation studies. Informed by the findings of a systematic review and a consensus-building e-Delphi exercise, an international working group of implementation science experts discussed and agreed the StaRI Checklist comprising 27 items. It prompts researchers to describe both the implementation strategy (techniques used to promote implementation of an underused evidence-based intervention) and the effectiveness of the intervention that was being implemented. An accompanying Explanation and Elaboration document (published in BMJ Open, doi:10.1136/bmjopen-2016-013318) details each of the items, explains the rationale, and provides examples of good reporting practice. Adoption of StaRI will improve the reporting of implementation studies, potentially facilitating translation of research into practice and improving the health of individuals and populations.

Globally, healthcare systems are struggling to deliver the benefits of research to their populations.1–3,5 Increasingly, it is recognised that translation from “bench to bedside to community”4 is often ineffective and inefficient. The scientific community needs to focus on how effective interventions are disseminated and implemented across the spectrum of contexts and settings in order to improve individual and population health.4 Against this background, implementation science has emerged as an important discipline for developing the evidence base on how to translate research findings into routine care.1–4 Implementation studies are, however, often poorly reported and indexed, making it difficult to find, reproduce, or synthesise the evidence from relevant studies.3 More specific criticisms include poor (or absent) description of conceptual frameworks underpinning the research,4 inadequate description of context, and incomplete information about how the intervention was promoted and implemented (or not) in the different settings.5–6

Similar concerns with, for example, the reporting of

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Data supplements on bmj.com (see http://www.bmj.com/content/356/bmj.i6795?tab=related#datasupp)

Appendix 1: e-Delphi results as provided to the workshop delegates
Appendix 2: Version of StaRI Checklist for completion by authors submitting an implementation paper

Supplementary references w1–w3

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randomised controlled trials (RCTs) led to the introduction of the Consolidated Standards of Reporting Trials (CONSORT) checklist, with evidence of subsequent improvement in reporting standards.

There have been calls for the development of similar standards for transparent and accurate reporting of implementation studies. The Standards for Reporting Implementation Studies (StaRI) initiative aimed to address this need.

### Scope and relationship with other reporting standards

Implementation science encompasses a broad range of methodologies applicable to improving the dissemination, implementation, and scaling up of effective behavioural, clinical, healthcare, public health, global health, and educational interventions (or discontinuation of ineffective or harmful practices) with a view to improving quality of care and health outcomes. Although this document is set within the context of healthcare and population health, there are parallels in other domains (such as educational initiatives).

The StaRI Statement and Checklist may thus have resonance outside healthcare.

Understanding of the position that implementation studies hold in the science of developing, evaluating, disseminating, and implementing healthcare interventions has been evolving over recent years. The UK Medical Research Council (MRC) Framework for Development and Evaluation of Complex Interventions emphasises the need to disseminate and implement findings of complex interventions but offers no advice on how to achieve this. PRECIS-2 conceives trial design on an “explanatory-pragmatic” spectrum but does not project beyond pragmatic trials to implementation in routine practice. Neither of these frameworks addresses the need for research to explore how interventions shown to be effective in trials require adaptation if they are to align with the routines of practice and be successfully implemented into “usual care” settings. Implementation science undertakes studies that explore healthcare contexts, develop and evaluate strategies for implementing effective interventions that address local realities, can be implemented at scale and are potentially sustainable. Proposed frameworks have added an “implementation cycle” to complement the MRC’s complex intervention cycle, or extended a linear spectrum (see fig 1). Others have emphasised the potential overlap between effectiveness and implementation research and described “hybrid” designs.

The StaRI Statement and Checklist are intended to improve reporting of implementation studies, employing a range of study designs to develop and evaluate implementation strategies with the aim of enhancing adoption and sustainability of effective interventions. Implementation studies may be distinguished from quality improvement reports that describe system level initiatives, typically in the context of a specific problem within a specific healthcare system, and the World Health Organisation guidelines, which focus on improving reporting of their fieldwork.

### Methods

We followed the methodology described in the Developing Health Research Reporting Guidelines. Our full protocol is available on the EQUATOR website. After a systematic literature review, we recruited international multidisciplinary experts (including healthcare researchers, journal editors, healthcare professionals and managers, methodologists, guideline developers, patient organisations, and funding bodies) to participate in an e-Delphi exercise. Of 66 experts approached, 23 contributed suggestions for the Checklist, 20 completed the first scoring round, and 19 completed the second scoring round. Of 47 potential items, 35 reached the a priori level of consensus for inclusion—that is, 80% agreement with priority scores 7, 8, or 9—and 19 items achieved 100% agreement. All these items, with their final priority scores, were taken forward as candidate items for inclusion in the StaRI Checklist.

In April 2015, we convened a two-day consensus working group in London attended by 15 international delegates (UK or Europe=11, US or Canada=4) drawn from multiple disciplines. Delegates included healthcare researchers (n=9), journal editors (n=6), healthcare professionals (n=8) and managers (n=1), methodologists (n=4), guideline developers (n=2), and funding bodies (n=2) (several participants had more than one role). This group discussed the candidate items and agreed the first draft of the StaRI Checklist. The discussions were informed by the outcome of the e-Delphi exercise (see appendix 1 for the e-Delphi results as provided to the workshop delegates), but items were also considered in the context of other published reporting standards and the wider literature, and the working group’s expertise in implementation science. After general discussion on key defining concepts (informed by points raised in the e-Delphi), each candidate item was considered in turn. Agreement was reached by discussion rather than by consensus scoring. The initial draft statement and documents were subsequently developed iteratively by email discussion.

Constructive feedback on a penultimate draft of the StaRI Statement from colleagues working internationally in the field of implementation science, healthcare researchers, clinicians, and patients was used to help shape the final version of the paper. In addition, we presented the concepts to and sought feedback from several workshops, conference discussions, and implementation project steering groups.

### Defining concepts

There are two defining concepts underpinning the StaRI Statement and Checklist. The first is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, global health, or public
Three overarching components are emphasized in the Checklist: provides examples of good practice. recommended that authors using the StaRI Checklist read the Explanation and Elaboration document published in BMJ Open. Appendix 2 is a version of the Checklist for completion by authors submitting an implementation paper. It is strongly recommended that authors using the StaRI Checklist read the detailed document that explains the rationale for each item and provides examples of good practice.

Three overarching components are emphasized in the Checklist:

1. The expectation is that authors have an explicit hypothesis (we use the term “logic pathway”) that spans both how the implementation strategy is expected to work and the mechanism by which the intervention is expected to improve health care (see Explanation and Elaboration document for a table of alternative terminologies and a link to a detailed description of “logic models”). This logic pathway should reflect the rationale presented in the introduction, determine the approach to implementation, dictate implementation, health, and process outcomes, and provide insights into why and how the implementation strategy and intervention worked (or not).

2. The balance between fidelity to, and adaptation of, the implementation strategy and intervention is of particular interest in implementation science. Fidelity refers to the degree of adherence to the described implementation strategy and intervention; adaptation is the degree to which users modify the strategy and intervention during implementation to suit the local needs (see table 2 for further description and examples). Insufficient fidelity to the “active ingredients” of an intervention may dilute effectiveness, whereas insufficient adaptation or tailoring to local context may inhibit effective implementation. An approach to reporting these apparently contradictory concepts is to define the core components of an intervention (ideally related to the logic pathway) to which fidelity is expected, and those aspects that may be adapted by local sites to aid implementation.

3. Successful implementation of an intervention into practice is a planned, facilitated process involving the interplay between individuals, intervention or new ways of working, and context to promote evidence-informed practice. A rich description of the context is critical to enable the reader to assess the external validity of the reported study, and to decide how the context in the study compares to their situation and whether the implementation strategy can be directly transposed or will need adapting. Similarly, social, political, and economic context influence the “entrenched practices” that hinder evidence-based de-implementation of unproven practices or interventions.

Discussion
Implementation science is an emerging and rapidly evolving field. The StaRI Statement and Checklist should therefore be seen as an evolving document, and potentially a catalyst for discussing and defining how implementation studies are conceived, planned, and reported.

We hope that the concept of dual strands will resonate with researchers designing and reporting implementation science studies. We appreciate that the distinction will not always be as unambiguous as it seems in the StaRI checklist, but we suggest that considering the design and evaluation of implementation studies in these two strands is helpful and aids clarity of study design and reporting. We also recognize that not all studies will measure health outcomes, though consideration of the ultimate goal of improving health through implementing an evidence-based intervention would seem a reasonable requirement. Feedback on this underpinning concept will be valuable for future iterations of the StaRI Statement and Checklist.

There are two practical challenges for the application of StaRI that warrant discussion. First, implementation science uses diverse methodologies that need to be accommodated in the reporting standards. One option is to incorporate relevant items from other checklists, but this may be perceived as limiting the methodological options. StaRI therefore advises authors to consult methodological checklists for reporting design-specific aspects of their chosen study design. By doing this, we have implicitly prioritized the concept underpinning implementation studies, though this should not be interpreted as undermining the rigour of reporting the chosen study design.

The second challenge is the requirement for extensive description of context, implementation strategies, and interventions as well as reporting a broad range of primary effectiveness, process, health, economic, and implementation outcomes. This requirement will stimulate debate about word counts, supplementary material, and additional publications in order to accommodate journal requirements, author needs, and

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Conclusion
The StaRI Statement is registered with the EQUATOR Network (www.equator-network.org), and the Checklist (for completion by authors) is freely available from bmj.com (appendix 2). We invite editors of all journals publishing implementation research to consider requiring submission of a StaRI Checklist, and authors reporting their implementation studies to use the Checklist. In the future we would like to work with authors as they apply the Checklist to their papers, “road testing” the standards and enabling iterative development.

Previously published reporting guidelines have been instrumental in improving reporting standards, and our hope is that StaRI will achieve a similar improvement in the reporting of implementation strategies that will facilitate translation of effective interventions into routine practice, ultimately to benefit the health of individuals and populations.

Members of the the StaRI Group are: Melanie Barwick, Chris Carpenter, Peter Craig, Sandra Eldridge, Eleni Epiphaniou, Gonzalez Grandes Orioizola, Chris Griffiths, Martin Gulliford, Jo Rycroft-Malone, Paul Meissner, Brian Mittman, Elizabeth Murray, Anita Patel, Gemma Pearce, Hilary Pinnock, Aziz Sheik, and Steph Taylor. Members of the PRISMS team (Eleni Epiphaniou, Gemma Pearce, and Hannah Parke) supported the underpinning literature work, and the e-Delphi exercise was handled by ClinVivo. We thank colleagues (implementation science experts, healthcare researchers, clinicians, PhD students) who reviewed the penultimate draft of the StaRI Statement and provided a reality check and constructive feedback: Helen Ashdown, David Chambers, Louise Craig, Clarisse Dibao-Dina, Peter Hanlon, Roger Jones, Rachel Jordan, Chris del Mar, Brian McKinsy, Susan Morrow, John Ovretveit, David Price, Kamran Siddiqui, Rafael Stelmach, Paul Stephenson, Shaun Treweek, Bryan Weiner. We also thank Melissa Goodburn and Alison Worth, who arranged feedback from the Edinburgh Clinical Research Facility Patient Advisory Panel (Stephanie Ashby, Alison Williams), and Steven Towndrow who coordinated feedback from the Patient and Public Involvement representatives of the NIHR CLAHR North Thames (Ben Wills-Eve, Rahilla Bashir, Julian Ashton, Colleen Ewart, Karen Williams).

Contributors: HP initiated the idea for the study and with ST led the development of the protocol, securing of funding, study administration, workshop, and writing of the paper. AS, CG, and SE advised on the development of the protocol and data analysis. All authors participated in the StaRI international working group along with GP, BM, MG, HP wrote the initial draft of the paper, to which all the authors contributed. HP is the study guarantor.

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Competing interests: All authors have completed the ICMEJ uniform disclosure form at www.icmej.org/oi披露 disclose.pdf and declare: research grants from Chief Scientist Office (HP), Asthma UK (AS, HP, ST), Farr Institute (AS), NIHR HS&D (HP, ST), NIHR CLAHRC (ST) for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; CC is deputy editor-in-chief for Academic Emergency Medicine and on the editorial boards for the Journal of the American Geriatrics Society and Annals of Internal Medicine’s ACP Journal Club and serves as paid faculty for Emergency Medical Abstracts, JR-M is director of the NIHR HS&D Programme, no other relationships or activities that could appear to have influenced the submitted work. Disclaimers: The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health. Provenance of the paper: The StaRI Checklist was informed by the findings of a literature review and an e-Delphi exercise, an international consensus workshop, and the subsequent email correspondence among members of the StaRI Group. The international authors contributed expertise on clinical practice, public health, knowledge exchange, implementation science, complex interventions, and a range of methodologies including quantitative and qualitative evaluations.


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### Linked information

- [StaRI website](http://www.equator-network.org/reporting-guidelines/stari-statement/)
- [Enhancing the QUAlity and Transparency Of health Research (EQUATOR)](http://www.equator-network.org/)
- [Consolidated Framework For Implementation Research (CFIR)](http://www.cfirguide.org/imp.html)
- [Logic models](http://www.wkkf.org/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide)
- [Dissemination and implementation models in Health Research and Practice](http://www.dissemination-implementation.org/index.aspx)
- [Process evaluation of complex interventions](http://www.ioe.ac.uk/MRC_PHSRN_Process_evaluation_guidance_final(2).pdf)
- [Reach Effectiveness Adoption Implementation Maintenance (RE-AIM)](http://www.re-aim.hrlte.vt.edu)
### Tables

**Table 1 | Standards for Reporting Implementation Studies: the StaRI Checklist of items to be reported**

<table>
<thead>
<tr>
<th>Checklist item</th>
<th>Implementation strategy</th>
<th>Intervention†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Identification as an implementation study, and description of the methodology in the title and/or keywords</td>
<td></td>
</tr>
<tr>
<td><strong>Abstract</strong></td>
<td>Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>Description of the problem, challenge, or deficiency in healthcare or public health that the intervention being implemented aims to address</td>
<td></td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td>The scientific background and rationale for the implementation strategy (including any underpinning theory, framework, or model, how it is expected to achieve its effects, effectiveness and how it is expected to achieve its effects) and any pilot work</td>
<td></td>
</tr>
<tr>
<td><strong>Aims and objectives</strong></td>
<td>The aims of the study, differentiating between implementation objectives and any intervention objectives</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>The design and key features of the evaluation (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere)</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>The characteristics of the targeted “site(s)” (locations, personnel, resources, etc) for implementation and any eligibility criteria</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>The population targeted by the intervention and any eligibility criteria</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>A description of the implementation strategy</td>
<td>A description of the intervention</td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed</td>
<td>Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed.</td>
</tr>
<tr>
<td><strong>Methods: description</strong></td>
<td>Document any pre-determined targets</td>
<td>Document any pre-determined targets</td>
</tr>
<tr>
<td><strong>Methods: evaluation</strong></td>
<td>Process evaluation objectives and outcomes related to the mechanism(s) through which the strategy is expected to work</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: evaluation</strong></td>
<td>Methods for resource use, costs, economic outcomes, and analysis for the implementation strategy</td>
<td>Methods for resource use, costs, economic outcomes, and analysis for the intervention</td>
</tr>
<tr>
<td><strong>Methods: evaluation</strong></td>
<td>Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: evaluation</strong></td>
<td>Methods of analysis (with reasons for that choice)</td>
<td></td>
</tr>
<tr>
<td><strong>Methods: evaluation</strong></td>
<td>Any a priori subgroup analyses (such as between different sites in a multicentre study, different clinical or demographic populations) and subgroups recruited to specific nested research tasks</td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Proportion recruited and characteristics of the recipient population for the implementation strategy</td>
<td>Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Primary and other outcome(s) of the implementation strategy</td>
<td>Primary and other outcome(s) of the intervention (if assessed)</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work</td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Resource use, costs, economic outcomes, and analysis for the implementation strategy</td>
<td>Resource use, costs, economic outcomes, and analysis for the intervention</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Representativeness and outcomes of subgroups including those recruited to specific research tasks</td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Fidelity to implementation strategy as planned and adaptation to suit context and preferences (where measured)</td>
<td>Fidelity to delivering the core components of intervention</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>Contextual changes (if any) which may have affected outcomes</td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>All important harms or unintended effects in each group</td>
<td></td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td>Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications</td>
<td></td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td>Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)</td>
<td>Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)</td>
</tr>
<tr>
<td><strong>General</strong></td>
<td>Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial or study registration (availability of protocol), funding, and conflicts of interest</td>
<td></td>
</tr>
</tbody>
</table>

*Implementation strategy refers to how the intervention was implemented.
†Intervention refers to the healthcare or public health intervention that is being implemented.
Table 1 (continued)

<table>
<thead>
<tr>
<th>Checklist item</th>
<th>Implementation strategy</th>
<th>Intervention†</th>
</tr>
</thead>
</table>

Note: A key concept is the dual strands of describing (a) the implementation strategy and (b) the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist. The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed. The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations. While all items are worthy of consideration, not all items will be applicable to or feasible within every study.
Table 2 | Terminology: definitions and illustration

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Definition</th>
<th>Illustration using a study implementing supported self management for asthma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementation science</td>
<td>The scientific study of methods to promote the systematic uptake of evidence-based interventions into practice and policy and hence improve health&lt;sup&gt;xvi&lt;/sup&gt;</td>
<td>Improving implementation in routine practice of evidence-based supported self management for asthma</td>
</tr>
<tr>
<td>Implementation strategy</td>
<td>Methods or techniques used to enhance the adoption, implementation, and sustainability of an under-utilised intervention&lt;sup&gt;xvii&lt;/sup&gt;</td>
<td>A programme of professional training, templates for reviews, access to resources, facilitation, audit, and feedback</td>
</tr>
<tr>
<td>Intervention</td>
<td>The evidence-based practice, programme, policy, process, or guideline recommendation that is being implemented&lt;sup&gt;xvii&lt;/sup&gt;</td>
<td>Provision of asthma self management in routine asthma reviews, including completion of action plans</td>
</tr>
<tr>
<td>Implementation outcome</td>
<td>Process or quality measure to assess the impact of the implementation strategy&lt;sup&gt;xvii&lt;/sup&gt;</td>
<td>Proportion of people with asthma who have an action plan</td>
</tr>
<tr>
<td>Health outcome</td>
<td>Patient-level health outcomes for a clinical intervention, such as symptoms or mortality; or population-level health status or indices of system function for a system/organisational-level intervention&lt;sup&gt;xviii&lt;/sup&gt;</td>
<td>Proportion of people with asthma requiring unscheduled care for asthma or patient reported asthma control</td>
</tr>
<tr>
<td>Logic pathway</td>
<td>The way(s) in which the implementation strategy and intervention are hypothesised to operate</td>
<td>An organisation that prioritises self management encourages or enables trained professionals to provide asthma action plans; self management improves asthma outcomes</td>
</tr>
<tr>
<td>Fidelity</td>
<td>The degree of adherence to the described implementation strategy and/or the degree to which an intervention is implemented as prescribed in the original protocol&lt;sup&gt;xix&lt;/sup&gt;</td>
<td>Uptake of professional training, utilisation of review templates (implementation fidelity), and assessment of adequacy of education and completion of action plans (intervention fidelity)</td>
</tr>
<tr>
<td>Adaptation</td>
<td>The degree to which the strategy and intervention are modified by users during implementation to suit local needs&lt;sup&gt;xix&lt;/sup&gt;</td>
<td>Use (or not) of telehealth to deliver reviews or provide action plans. Different professionals (doctors, nurses, pharmacists) with primary responsibility for self management education</td>
</tr>
</tbody>
</table>
Figure

StaRI is targeted on the reporting of interventional implementation studies (the dark shaded box) but will have resonance for studies in the pilot and sustainability phases.

**Fig 1** Positioning of implementation studies and the focus of StaRI reporting standards (adapted from fig 12.1. in Brownson et al\textsuperscript{8})