Title: The Reporting recommendations Intended for pharmaceutical risk Minimization Evaluation Studies: Standards for Reporting of Implementation Studies Extension (RIMES-SE).

Journal: Drug Safety

Authors: Smith MY, Morrato EH, Mora N, Nguyen V, Pinnock H, Winterstein AG

Corresponding Author: Meredith Y Smith, Evidera Inc., tantmieux57@gmail.com

Supplementary File 1. RIMES-SE eDELPHI Survey: Round 1

The goal of this eDelphi exercise is to develop a checklist for reporting results of risk minimization program evaluations. This checklist is intended to facilitate comprehensive, standardized reporting of these studies so as to permit synthesis of the research literature and, ultimately, to advance the science by providing greater understanding of what types of programs work most effectively for whom and under what conditions. You have been invited to participate because you are a recognized subject matter expert in drug safety, risk minimization, pharmacoepidemiology and/or implementation science.

This eDelphi exercise will consist of two rounds of expert review. In Round 1, you will be asked to rate each of the following items in terms of their 1) importance for inclusion in a quality reporting checklist, and 2) understandability. These items were generated via a review of the published risk minimization evaluation literature, and from a review of items contained in the **Sta**ndards for **R**eporting of **I**mplementation studies (StaRI), a quality reporting checklist for implementation science studies. Our goal is to create a quality reporting checklist for risk minimization evaluation studies that is an extension of the StaRI. It will be entitled the **R**eporting recommendations **I**ntended for pharmaceutical risk **M**inimization **E**valuation **S**tudies (RIMES) statement-StaRI Extension or RIMES-SE.

If you wish to participate, please click YES in the box below in order to proceed. All of the information collected will be kept confidential. Results will be presented in a collated manner and will not be linked to any individual respondent. If you do agree to participate, it is very important that you complete both rounds in order for us to achieve a high quality level of consensus.

Yes, I agree to participate. ☐ No, I decline to participate. ☐

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1. Before we begin, could you please identify your area of expertise (check all that apply):

☐ Implementation Science/Knowledge Translation

☐ Pharmacoepidemiology

☐ Pharmacovigilance/Drug Safety

☐ Other _____

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2. What sector(s) have you worked in? (check all that apply):

☐ Government/Regulator

☐ Academia

☐ Industry

☐ Research Consultancy

☐ Other _____

I. Item Importance Rating: *Please rate the importance of including each item listed below in the quality reporting checklist.*

Item	Importance Rating
ITEM 1: Identification as a risk minimization evaluation study, and description of the study design, name of medicinal product and target population/healthcare setting in the title (all 3 required). *Example: A drug utilization study to assess dispensing patterns at pharmacies for [drug name].* Specify also that it is an implementation evaluation and describe the methodology either in the title and/or as keywords. INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 2: Identification as a risk minimization evaluation study, including a description of the implementation strategy/ies to be tested, the evidence-based intervention being implemented, target recipient(s), evaluation methods, and the key implementation and health outcomes, results, and conclusions. INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 3. Description of the problem, challenge, or deficiency in healthcare or public health that the intervention being implemented aims to address. INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 4a. The scientific background and rationale for the implementation strategy (including any underpinning theory/ framework/model, how it is expected to achieve its effects and any pilot work). INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important

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ITEM 4b: The scientific background and rationale for the intervention being implemented (including the theory/framework/model(s) used to design the intervention and/or risk minimization tools, any evidence (e.g., pilot studies) regarding its effectiveness and the expected causal pathway for intervention impact). INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 5. The aims of the study, differentiating between implementation objectives and intervention objectives. INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 6: The goals/objectives of the risk minimization evaluation study (including any hypotheses), design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards), date of implementation of risk minimization intervention, and any changes to evaluation (or "assessment") plan, with reasons. *Example: We hypothesized that, as a result of distributing a brochure, 80% of physicians who prescribed [drug name] would correctly identify the three key steps involved in screening patients for low blood pressure prior to initiating [drug name] therapy.* INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 7. The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organizational barriers, and facilitators that might influence implementation elsewhere). INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 8a. The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 8b: The population targeted by the intervention and any eligibility criteria. Example: The risk minimization program targeted at US adults (aged 18 years+) who have been prescribed [drug name] for the treatment of cardiovascular disease. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 9a. A description of the implementation strategy, including modality/ies for tool dissemination, whether stakeholder engagement was used to design the intervention and implementation strategies. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 9b: A description of the intervention strategy, including the risk minimization tool(s) (Example: The risk minimization tools included a Dear HealthCare Professional Letter, and a Benefit-Risk	

Counseling tool for physicians); risk minimization tool content (could be included in an online supplement or appendix; Example: Information on [drug name] risks, symptoms to watch for, and actions to take if symptoms presented themselves), distribution modality/ies *(Example: The tool was intended for distribution via Medscape email to physicians, journal advertisements, and a website posting), and, whether tools were pilot-tested (Add a note if the latter is 'Unknown').* METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 10a. Defined pre-specified primary and other outcome(s) of the implementation strategy, how they were assessed, and sources of data and methods of measurement. Document any predetermined targets. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 10b: Defined pre-specified primary and other outcome(s) of the intervention (if assessed), how they were assessed, and sources of data and methods of measurement. Document any predetermined targets. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 11a. Process evaluation measures prespecified as a goal of the evaluation (e.g., reach, adoption, dose delivered, fidelity of implementation) and how they were selected and assessed. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 11b. Outcome measures, how they were selected and assessed, and whether there was a specified link between evaluation study goals and methods. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 12. Description of risk minimization activities versus usual care (for example, cost, time, skills required) for patients, providers, and/or healthcare settings to ascertain degree of burden imposed on healthcare system due to introduction of new risk minimization program. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 13. Rationale for sample size (including effect size estimate, budgetary constraints, practical considerations, data saturation, as appropriate). METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important

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ITEM 14. Methods of analysis (with reasons for that choice), including explanation of how missing data were handled. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 15. Any a priori sub-group analyses (e.g., between different sites in a multicenter study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 16a. Proportion recruited and characteristics of the recipient population for the implementation strategy. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 16b. Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention, including a table showing baseline characteristics of the evaluation study participants and settings (e.g., demographic, clinical, social, setting type, number, and locations. METHODS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 17a. Primary and other outcome(s) of the implementation strategy. RESULTS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 17b. Primary and other outcome(s) of the Intervention (if assessed), including precision of report of outcomes, and description of whether primary outcome(s) exceeded a pre-specified success threshold. RESULTS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 18. Description of added time/procedures/processes incurred as a result of the introduction of the risk minimization program as compared to usual care. RESULTS	1 2 3 4 5 6 7 8 9 10 Not At all Important — Extremely Important
ITEM 19. Representativeness and outcomes of subgroups including those recruited to specific research tasks. RESULTS	1 2 3 4 5 6 7 8 9 10 Not At all — Extremely Important

	Important
ITEM 20a. Fidelity to implementation strategy as planned and adaptation to suit context and preferences (including whether any training was provided to implementers regarding the intervention and how to implement it, and use of a formal protocol for implementing the intervention). DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 20b. Fidelity to delivering the core components of intervention (where measured at the global and at the local country levels). Note: Add a statement specifying if fidelity to implementation strategy and/or fidelity to delivery of core components is unknown. DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 21. Contextual changes (if any) which may have affected outcomes (including description of any factors that served to impede or facilitate intervention adoption and implementation). DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 22a. All-important harms or unintended effects in each group. DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 22b. Results of any other analyses performed, including subgroup analyses, interactions, and sensitivity analyses, distinguishing pre-specified from exploratory and identification of unintended impact(s) of the risk minimization intervention or the evaluation study.	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 23. Summary of findings (including whether primary outcome(s) exceeded a specified success threshold), strengths and limitations, comparisons with other studies, conclusions and implications. DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 24. Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability) AND Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability). DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not Extremely At all Important Important
ITEM 25. Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data,	1 2 3 4 5 6 7 8 9 10 Not Extremely

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governance approval), trial/study registration (availability of protocol), funding and conflicts of interest. DISCUSSION	At all Important Important

II. Understandability: *Please rate the understandability of each item listed below for inclusion in the quality reporting checklist.*

Item	Importance Rating
ITEM 1: Identification as a risk minimization evaluation study, and description of the study design, name of medicinal product and target population/healthcare setting in the title (all 3 required). *Example: A drug utilization study to assess dispensing patterns at pharmacies for [drug name].* Specify also that it is an implementation evaluation and describe the methodology either in the title and/or as keywords. INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Understandable Extremely Understandable
ITEM 2: Identification as a risk minimization evaluation study, including a description of the implementation strategy/ies to be tested, the evidence-based intervention being implemented, target recipient(s), evaluation methods, and the key implementation and health outcomes, results, and conclusions. INTRODUCTION	1 2 3 4 5 6 7 8 9 10 Not At all Understandable Extremely Understandable
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ITEM 24. Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability) AND Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability). DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not At all Understandable ... Extremely Understandable
ITEM 25. Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest. DISCUSSION	1 2 3 4 5 6 7 8 9 10 Not At all Understandable ... Extremely Understandable

Thank you for your participation!