A Qualitative Assessment of the STROBE Extensions: Laying the Groundwork for Future Educational Interventions

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Introduction

- The STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) guideline was developed in response to inadequate reporting of observational studies
- In recent years, several extensions to STROBE have been created to provide more nuanced field-specific guidance
- This evaluation aims to classify the changes made in the extensions in order to identify areas of STROBE that were changed and the level of specificity of the changes.
- Areas that are not-field specific or reflect general epidemiological, methodological or statistical tenets may indicate areas in need of clarification in the original STROBE checklist

Methods

13 STROBE extensions were assessed:

- **STREGA** (genetic association studies)
- **STROBE-EULAR** (rheumatology)
- **STROBE-ME** (molecular epidemiology)
- **STROME-ID** (infectious disease molecular epidemiology)
- **STROBE-RDS** (response-driven sampling)
- **RECORD** (routinely collected health data)
- **STROBE-AMS** (anti-microbial stewardship)
- **MARE-S** (medical abortion)
- **STROBE-NUT** (nutritional epidemiology)
- **ROSES-I** (seroepidemiology for influenza)
- **STROBE-SBR** (simulation-based research)
- **STROBE-NI** (newborn infection)
- **STROBE-Vet** (veterinary)

Two independent researchers assessed additions in each extension. Intra-class correlation was calculated to measure agreement (ICC=0.92). Individual additions were grouped by STROBE checklist item and coded as "field-specific" (FS) or "not field-specific" (NFS).

- **FS:** particularly relevant information for a singular field; guidance provided generally cannot be extrapolated outside of that extension's field
- **NFS:** information that reflects a general epidemiological tenet; can be extrapolated to most, if not all, types of observational studies

Results

297 additions were made across 13 extensions. 36.7% of items were non-specific.

Top 5 Areas Changed

- Statistical Methods: 44 additions (45.5% not field-specific)
- Participants: 29 additions (41.4% NFS)
- Variables: 28 additions (32.1% NFS)
- Setting: 20 additions (14.3% NFS)
- Study design: 18 additions (5.3% NFS)

Largest Percentage of NFS Recommendations

- "Other Additions": 10/12 (83.3%)
- Bias: 4/5 (80%)
- Other Analyses: 5/8 (62.5%)
- Study Size: 3/5 (60%)
- Main Results: 9/16 (56.2%)

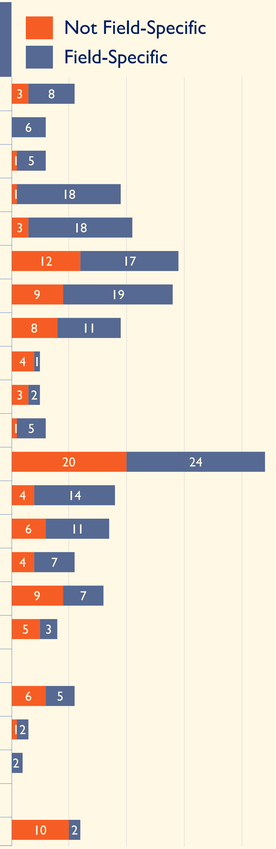
Examples of Field-Specific Guidance

- *State whether this is an outbreak study, and if so define an outbreak, with reference to an international standard*
- *Clearly define genetic exposure (genetic variants) using widely used nomenclature system….*
- *List simulator brand and if conflict of interest for intellectual property exists.*

Examples of Not Field-Specific Guidance

- *Include description of potential confounders (other than epidemiological variables).*
- *Discuss implication of unmeasured/residual confounding*
- *Describe subjects who changed exposure status*
- *Authors should provide information on how to access any supplementary information such as the study protocol or programming code*
- *If detailed results are available elsewhere, state how they can be accessed*

Section on STROBE Checklist	STROBE Checklist Item	Total Added	Field Specific Items, No. (%)
Title/Abstract	1. Title/Abstract	11	8 (72.7)
Introduction	2. Background/Rationale	6	6 (100)
	3. Objectives	6	5 (83.3)
Methods	4. Study Design	19	18 (94.7)
	5. Setting	21	18 (85.7)
	6. Participants	29	17 (58.6)
	7. Variables	28	19 (67.9)
	8. Data Sources	19	11 (57.9)
	9. Bias	5	1 (20.0)
	10. Study Size	5	2 (40.0)
	11. Quantitative Variables	6	5 (83.3)
	12. Statistical Methods	44	24 (54.5)
Results	13. Participants	18	14 (77.8)
	14. Descriptive Data	17	11 (64.7)
	15. Outcome Data	11	7 (63.6)
	16. Main Results	16	7 (43.8)
	17. Other Analyses	8	3 (37.5)
Discussion	18. Key Results	0	0 (0)
	19. Limitations	11	5 (45.5)
	20. Interpretation	3	2 (66.7)
	21. Generalisability	2	2 (100)
Other	22. Funding	0	0 (0)
	Other Additions	12	2 (16.7)



Conclusions

Over 1/3 of all recommendations were not field-specific. The methods section contained the most changed items and several items from this section also contained many non-specific changes

From all the additions made, we identified several redundant recommendations. These include:

- Suggestions for ethics disclosure/approval
- Provision of information on how to access to supplemental information such as open source data, code, study protocols, etc.
- More information on subgroup and sensitivity analyses
- More information describing the participants, including changes in exposure status, timepoints of assessment for longitudinal studies, recruitment details (generalizability)
- More information about potential confounders and biases

Results highlight gaps in understanding of epidemiological principles or in STROBE guidance. Alternatively, it could represent perceived inadequacies of the STROBE checklist which, similar to CONSORT, could warrant revision.

Next steps: We are currently working on a bibliometric study assessing the prevalence of extension endorsement. We also plan on surveying authors on their use of STROBE and ultimately creating an educational intervention for authors reporting results from observational studies.

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