

STRATOS Publication Panel

Guidance on STRATOS publication policies: Version 9.0

December 16, 2019

This document outlines the proposed structure and activities of the STRATOS Publication Panel (PP). It should be noted that this document outlines *guidance* for publications in STRATOS, and it is *not* intended as a set of rigid regulations. Rather, we adopt the ICMJE guidelines for authorship to make it suitable for STRATOS publications (e.g. <http://journals.plos.org/plosmedicine/s/authorship#loc-group-authorship>)

The STRATOS Visualisation Panel (VP) offered to provide guidance for visualisations in STRATOS papers. For details see the addendum from the STRATOS Visualisation Panel.

Please see 4.2 and 4.3 for the process of the PP and VP involvement.

The international STRengthening Analytical Thinking for Observational Studies (STRATOS) initiative (<http://stratos-initiative.org>) aims to provide accessible and accurate guidance documents for relevant topics in the design and analysis of observational studies.

1. Membership of the Publication Panel

Currently the panel members are

- Chairs: Bianca De Stavola (b.destavola@ucl.ac.uk), Pamela Shaw (shawp@upenn.edu)
- Co-chairs: Mitchell Gail (gailm@exchange.nih.gov), Petra Macaskill (petra.macaskill@sydney.edu.au)
- One person to be nominated by each TG:
 - TG1– TBA.
 - TG2 Rolf Groenwold
 - TG3 Marianne Huebner

- TG4 Pamela Shaw
 - TG5 Mitchell Gail
 - TG6 Petra Macaskill
 - TG7 Bianca De Stavola
 - TG8 Jeremy Taylor
 - TG9 Joerg Rahnenfuehrer
 - One person from the literature review panel
 - Simon Day (Glossary panel, GP)
 - Suzanne Cadarette (Knowledge Translation Panel, TP)
- Willi Sauerbrei

2. Terms of reference

2.1 Defining a STRATOS publication

This guideline will apply to papers appearing in journals, letters to the editor, reports, books, and potentially to other types of communication.

2.1.1 A STRATOS publication will:

- Usually include at least two (but usually three or more) authors who are STRATOS members; an exception might be made in the case of papers with a single author (who is a STRATOS member) that can be regarded as “subsidiary” papers, for example papers that refer to earlier, multi-authored papers from a given TG.
- Have authors who wish to indicate some affiliation with STRATOS in the publication itself.
- Intend to be submitted on behalf of a TG, panel or the STRATOS initiative.
- Be reviewed and approved by the Publication Panel.

In the case of papers authored in the name of one or more topic groups or a panels, the corresponding TG or panel chairs must at least endorse the paper or be co-authors. This is to avoid the case that some people could express their personal opinions in a STRATOS paper, but without STRATOS agreement. *In the rare case of a single author paper, the corresponding TG or panel*

chairs must support it with a statement summarizing the main context of the paper and giving the main reason that a single author writes in the name of a TG or panel.

In the case of papers authored in the name of STRATOS, all members of the Executive Committee must at least endorse the paper.

2.1.2 A STRATOS associated publication will:

- NOT be submitted on behalf of a TG, panel, or of the STRATOS Initiative
- have at least one author who is a STRATOS member
- mention the name STRATOS Initiative
- discuss relevant topics to the STRATOS Initiative

Such a publication may be auxiliary to a STRATOS publication, discussing subtopics in more depth, or addressing other audiences.

2.1.3 Papers will be identified by authors to the PP as being:

- for Level (1, 2 or 3, see appendix) – or some mixture of level 2 and 3 -, and
- if they are intended to be relevant for
 - Guidance
 - Exposition
 - Research
 - Other

2.2 Defining how the name STRATOS can be used in publications

2.2.1 For papers, STRATOS might be mentioned in a number of ways, including:

- In the title or otherwise shown prominently.
- As a footnote or acknowledgement.
- As a mention in the text.
- Individual authors (possibly not all the authors in a given paper) are identified as STRATOS members as part of their affiliation information.
- If possible (according to the journal’s format requirements), the term “STRATOS initiative” might be mentioned as a keyword.

- Typical formats for authorship might be: “X1, X2, X... on behalf of TGy of the STRATOS initiative”, or “X1, X2, X... on behalf of the STRATOS initiative”. To explain the STRATOS initiative in the paper, please use the boxed text at the beginning of this document.

2.2.2 For letters, STRATOS can be mentioned as follows:

- X1, X2, X3...for TGx/panel Z (and TGy) of the STRATOS initiative. It is not required that TG or panel chairs be authors, but they should have agreed.
- X1, X2, X3... (indicating STRATOS affiliation). PP has to agree but not the corresponding TG chairs.

Letters are often on contentious issues, and they may not go through the review process that a regular article does. They may require consultation among TG chairs to get agreement. It may be inappropriate to put the STRATOS label on letters unless there is adequate time to vet them broadly. However, if the letter concerns a minor technical point, such vetting might not be needed.

2.2.3 Presentations: Authorship guidelines for talks follow the same rules as for STRATOS publications. Presentations related to TGs require agreement of TG chairs. Overall STRATOS presentations should be reviewed by the TG chairs or PP as appropriate. An early version is requested three weeks prior to the presentation.

2.2.4 Websites. There are currently no defined policies on the use of STRATOS name on webpages. It is possible that individual STRATOS members identify themselves as such on their professional webpages with an explanation of the STRATOS initiative (using the boxed text at the beginning of this document). Other mentions should be approved by the PP or TP. Website guidelines will be primarily the responsibility of the corresponding TG or panel chairs.

2.2.5 Other types of publication: the guidelines above will apply to other communications, such as working papers, books, monographs, reports, videos or apps.

2.3 Target journals

In Banff 2016, it was suggested that we identify about 5 journals for each of level 1 and 2 and try to concentrate our publications there, but this idea did not receive strong support. The possibility of establishing formal relationships with some journals was also mentioned. These relationships might include feature such as open access discounts. Appropriate target journals might be those publishing applied statistical methods, or might be defined as important in certain areas of application (e.g. health services, epidemiology). We did not get to the stage of identifying specific journals to be targeted, but the following were mentioned: JCO, JNCI, AJE, BMJ, AIM (for level 1), and SIM, J Clin Epid., BMJ Med Research Methods, Stat Methods in Med Research (for level 2) but authors are not restricted to submitting to these journals. This issue is less relevant for level 3 papers.

We have discussed the possibility of establishing ongoing relationships with certain journals so that, for instance, we might envisage their publication of “occasional series” of papers associated with STRATOS. Taking this kind of initiative will primarily be the responsibility of TGs.

3. Reviews of STRATOS papers

If authors intend to affiliate their publication with STRATOS in any way, it may need to be internally reviewed by independent members of STRATOS (or external people, as necessary – see below).

3.1 Goals of the review process by the PP

The PP will not act as an editorial board, but its review process will have several goals:

- 3.1.1 Try to assure that terminology is consistently used across all STRATOS papers (this will require input from the Glossary panel).

- 3.1.2 Evaluating how well the goals of STRATOS are satisfied (e.g. communicating clearly to a defined target audience). This will depend to some extent on the type of paper involved (e.g. level 1 vs. 2 vs. 3).
- 3.1.3 Evaluating scientific content. This is going to be much more difficult because PP members may not have enough relevant background knowledge. A prime resource here will be the representative of the appropriate TG on the PP – assuming that this person is not already involved with the paper. The purpose of the PP review is not to examine the scientific content in detail (that would be the responsibility of the journal referees and editors), but rather to assess compatibility with STRATOS objectives.
- 3.1.4 Many issues and recommendations are relevant for more than one TG, and we will try to ensure that there is coherence between TGs, and try to prevent contradictions between recommendations from different TGs.
- 3.1.5 For some Guidance papers, there may be more than one point of view on the most appropriate methods to recommend. Authors should make sure to discuss the existence of alternative approaches, together with a discussion of relative strengths and weaknesses.
- 3.1.6 Giving general guidance on authorship principles. PP will encourage the authors to agree on order of authorship and allocation of responsibilities beforehand, to the extent possible. General principles for authorship include requiring that the author contribute to the work actively and assigning authorship position based on contributions. Not all authors need to be members of STRATOS. The usual “rules” for publications (IJCME) should apply, i.e. anyone who contributes significantly should be named as an author, regardless of STRATOS status. As a specific example, an author could be someone who has contributed to the initial discussions and conceptualisation of a paper, but not involved in detail thereafter. We also note that students and junior researchers can be included as authors. Many journals will ask for a statement from authors about their contributions to a paper, to ensure that generally accepted authorship principles are being followed.

3.2 General requirements for STRATOS papers

3.2.1 Level 1-2 papers

Results need to be reproducible and papers should be Open Access. Sample data and software need to be made available, with links (or content) provided on the STRATOS website. Realisation data from simulation studies would be an exception. It is best to separate data and software. For the illustration of new methodology, we strongly encourage authors to use publicly available data.

3.2.2 Level 3 papers

Papers should preferably be Open Access and results should ideally be reproducible. Papers should not be too technical, i.e. accessible to a broader community of experts (such as other TG members).

4. Process of the PP involvement

Authors must have PP approval to submit a STRATOS publication (as defined above). Papers indicating an affiliation with STRATOS should not be submitted before getting PP approval.

4.1 STRATOS authors should contact PP as early as possible, with at least a preliminary draft of their paper. This will help to clarify the type of review required, and identify any major issues early on.

4.2 Please send the draft of the paper to the Chair(s) and co-Chair(s) of PP.

4.3 The Chair(s) or co-Chair(s) of PP will determine the type of review required, and identify suitable individuals to carry out the review (if any). For information the work will be circulated to all PP members and to the chairs of VP. Concerning VP involvement see an addendum.

4.4 PP members may be able to review some papers themselves, but more technical papers (in level 3, and possibly level 2) will probably require input from researchers with specialised content knowledge. The appropriate TG representative on PP would be an obvious choice to do the review, if he/she could do so independently. Otherwise we may rely on the TG to suggest external persons (preferably STRATOS members) whom we might co-opt for this purpose.

- 4.5 The depth and type of review that is needed will vary. Some papers may require a more detailed review (STRATOS paper 2.1.1, STRATOS associated paper 2.1.2). Little scientific review may be required for level 3 papers.
- 4.6 If a paper merely alludes to STRATOS in the text as a motivation for the work, it would not need to be reviewed by PP.
- 4.7 It may be desirable for a level 1 guidance papers to be reviewed by somebody in the target area of application, such as somebody with a clinical background.
- 4.8 Up to 3 weeks would usually be required for PP to carry out the review, so authors should avoid the situation of only contacting PP at the stage when they are ready to submit their paper to a journal (or elsewhere).
- 4.9 Feedback from PP to authors should be brief, and a detailed review is definitely not required. The feedback in most cases will essentially be an “approve/reject” result, possibly with a few bullet points to explain the rationale. In the case of a “rejected” paper, further negotiation will be needed to gain STRATOS endorsement.
- 4.10 The PP may be able to provide a letter of general support describing the STRATOS initiative, which could be sent, at the discretion of the authors, to the editors of the target journal for the paper.

5 Process after submission of publications or presentations:

- 5.1 Revised papers need not be resubmitted to the PP.
- 5.2 Authors should inform PP and TP of accepted papers.
- 5.3 Authors/Presenters should submit final version of paper or presentation slides to PP and STRATOS Chairs.
- 5.4 Authors will be encouraged to propose a knowledge translation plan once published (e.g., conference presentation, slide share, twitter strategy, short webinar to summarize contents). TP will advise.

6 Other issues

At the moment, we have not set a time limit for membership on PP, or established how we might replace members who resign.

APPENDIX

Level of STRATOS papers (<http://www.stratos-initiative.org>)

Level 1: Low statistical knowledge

We have to assume that most analyses are done by analysts at that level. It is important to point out weaknesses of approaches which are often used despite of problems (eg categorizing continuous variables in the analysis; complete case analysis if some variables have missing values) and to propose methods which may not be optimal or state of the art, but which are easy to use and which are still acceptable from a methodological point of view. Required software should be generally available.

Level 2: Experienced knowledge

Here we should point to methodology which is perhaps slightly below state of the art, but doable by every experienced analyst. We should refer to advantages and disadvantages of competing approaches, point to the importance and implications of underlying assumptions, and stress the necessity of sensitivity analyses. If these issues are well understood it is most likely that a sensible analysis strategy is chosen for the specific question. Sufficient guidance about software plays a key role that this approach is also used in practice.

Level 3: Expert in specific area

To improve statistical models and to adapt them to complex problems in reality researches develop new and more complicated approaches. However, usually it is unclear whether the use of such an approach has relevant advantages in practice. Most often, advantages are presented in a small number of examples and in specific situations, but a more systematic comparison to the state-of-the-art is missing. Software requires specific knowledge and is not generally available.

This level would give an overview of recent research with statements about possible advantages and disadvantages of the approaches. It could help to identify important weaknesses when using level 2 proposals in more specific situations. It will certainly help to identify areas needing more methodological research and would trigger the development of software for more general use.

STRATOS Visualisation Panel

Addendum to the STRATOS Publication Panel

December 10, 2019

This document outlines the proposed structure and activities of the STRATOS Visualisation Panel (VP). It should be noted that this document outlines *guidance* for visualisations in STRATOS, and it is *not* intended as a set of rigid regulations. Rather, we promote the use of good graphical principles for effective visual communication by STRATOS publications. The VP will also provide guidance and recommendations on how to design, implement and review effective visualisations. See the website for details.

The international STRengthening Analytical Thinking for Observational Studies (STRATOS) initiative (<http://stratos-initiative.org>) aims to provide accessible and accurate guidance for relevant topics in the design and analysis of observational studies.

1. Membership of the Visualisation Panel

Currently the panel members are

- Chairs: Mark Baillie (mark.baillie@novartis.com)
- Co-chairs:
- Members:
- Tim Morris (tim.morris@ucl.ac.uk)
- Marc Vandemeulebroecke (marc.vandemeulebroecke@novartis.com)
- Svenja Seide (seide@imbi.uni-heidelberg.de),
- Willi Sauerbrei

An up-to-date list of VP panel members is located at <http://www.stratos-initiative.org/node/61>.

2. Reviews of STRATOS papers: parallel review of visualisations

In parallel to the PP review, a review focusing on data visualisations may be performed by the VP. The PP will send the paper to chairs of VP. VP will send recommendations to the authors, with a cc to PP. Authors can decide whether they follow any of the proposals from VP or whether improvements would be less substantial and will not lead to any changes.

3.1 Goals of the review process by the VP

The VP will not act as an editorial board, but its review process will have several goals:

- 3.1.1 Try to assure that all visualisations used across all STRATOS papers communicate clearly and effectively to the defined target audience. This will depend to some extent on the type of paper involved (e.g. level 1 vs. 2 vs. 3).
- 3.1.2 The statistical and quantitative information are aligned to a clear purpose (i.e. what is the question the visualisation is addressing).
- 3.1.3 The quantitative evidence to answer the question of the target visualisation is addressing, and any important underlying assumptions, are clearly stated.
- 3.1.4 The intended audience has been identified (e.g. level 1 vs. 2 vs. 3) and the focus of the visualisation designed to support their needs.

3. Process of the VP involvement

Refer to section 4 of the STRATOS Publication Panel document.

The following proposed extensions to the STRATOS Publication Panel process are proposed to facilitate the addition of a parallel VP review.

“4.3 The Chair(s) or co-Chair(s) of PP will determine the type of review required, and identify suitable individuals to carry out the review (if any). The work will be circulated to all PP members for information. **If the paper contains data visualisations the work will also be circulated to the Chair(s) of the VP**”

1. The Chair(s) of VP will determine the type of review required, and identify suitable individuals to carry out the review (if any). The work will be circulated to all VP members for information.
2. Comments and recommendations from VP will be sent to the PP in a timely manner to ensure collated feedback to authors. Proposals should be brief, and where possible illustrative examples provided explaining the rationale and recommendation to help facilitate updates. The feedback from the VP will be non-binding.

4 Process after submission of publications or presentations:

Refer to section 5 of the STRATOS Publication Panel document.

5 Other issues

At the moment, we have not set a time limit for membership on VP, or established how we might replace members who resign.