



PAIN OUT Project: Publication Strategy and Plan

Introduction

The aim of this document is to:

- (1) Layout a strategy and guidelines of how collaborators taking part in the PAIN OUT project will have access to data (their own and multi-center) in the PAIN OUT repository for the purpose of preparing abstracts, posters, talks given at scientific meetings and manuscripts for publication in peer reviewed journals.
- (2) Facilitate that collaborators taking part in PAIN OUT will use the data to create new knowledge and share it with other providers by publishing it.
- (3) Describe an outline for publications planned from this project.
- (4) Ensure that access and use of data is transparent and fair to all collaborators taking part in the project.

This plan aims to comply with internationally accepted guidelines for authorship established by the International Committee of Medical Journal Editors (<http://www.icmje.org/>) and Company sponsored medical research (Battisti et al, 2015).

- **Publication of any results obtained during the PAIN OUT project – including preliminary results - requires written permission from the Publication Board.**
- **Once permission is received and data sent, the data agreement restricts use of data for the single requested analysis; the data may not be used for preparing additional analyses and publications.**

Publication Board

Members of the Publication Board (PB) will be members of the PAIN OUT coordination team. For publications derived from data collected in national PAN OUT networks, the network leaders or their representatives, will join the publication board for work related to that network.

Publications arising from the PAIN OUT project in national networks

We aim for several publications which will describe the **primary outcome(s)** of the study. These will be followed by publications addressing **secondary outcomes**, exploratory analyses or post-hoc analyses using multi-center data from PAIN OUT OR a national network OR a single center within a network.

Proposed topics for **primary publications**

1. Implementing quality improvement measures for perioperative pain within a national network(s) (describing the program) and the current status quo of perioperative pain management and patient reported outcomes (descriptive – summary of the baseline data collected in the networks).
2. Results from implementing quality improvement measures for perioperative pain in a national network(s)

In some networks, both topics may be relevant, in others, only the second.

Collaborators may suggest additional topics as primary publications.

A project consisting of a network or several networks, will involve a large multi-author group. Authorship of the primary publications will be based on a **group name**, with or without the names of individuals, as described by the International Committee of Medical Journal Editors (ICMJE).

The corresponding author will clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article will identify who is directly responsible for the manuscript. MEDLINE lists as authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.



We will aim that:

- at least one name per center will be cited in the group as author.
- other names can be cited as authors or collaborators.

Authorship will be based on the recommendations of the ICMJE.

The ICMJE recommends that authorship be based on the following 4 criteria:

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The final order of names will be based on the author's actual roles and contributions in the development of the publication and so will be agreed upon once the publication is complete.

The PB will choose the group name and will determine the criteria for including a hospital / PI / surveyor / members of the multi-disciplinary working group into the group name.

Secondary publications can be initiated by any collaborator in the PAIN OUT project, a principal investigator OR surveyor OR member of the local multidisciplinary committee.

The purpose of sending a proposal to the PB is mainly to prevent duplications and that two or more groups will work simultaneously on the same topic.

Topics for these secondary publications should be ones that do not overlap with those planned for the primary publication(s).

Procedure for collaborators wishing to use multicenter data for a secondary publication

1. The collaborator will prepare a proposal consisting of the following: proposed title, research question, variables to be used, statistical methods, target journal, time schedule (but not longer than six months until first submission), lead authors (first and last). See template in appendix 1.
2. The proposal will be sent to Ruth Zaslansky who will then ask the PB to assess whether it overlaps with existing proposals and to assess for major methodological flaws, such as those that might result in presenting the PAIN OUT project and \ or its results in an erroneous manner.
3. Overlap occurring between topics suggested by different collaborators will be discussed and moderated by the PB until a satisfactory outcome is reached.
4. A proposal accepted by the PB will be posted on the PAIN OUT website, in the Publication Board section\ Proposals and the PAIN OUT coordination office will send an e-mail alerting all PAIN OUT collaborators that a new proposal has been posted. Requests for collaboration or objections related to the study can then be submitted within 10 days.
5. After these 10 days, the lead author can sign the Data Use Agreement and will receive the data
6. Centers contributing a sizeable number of datasets for the study will be listed in the acknowledgement section of the publication.
7. Criteria for authorship in a secondary publication can be either by group name OR as individual authors. The decision will be made by the collaborators participating in preparing the publication.
8. If a topic that was proposed is not submitted as a manuscript within the planned time, the topic may be taken over by a different group.
9. Once the planned publication is published, the lead author will be responsible for sending a copy to the



PAIN OUT coordinator's office for the project's records.

- Any misunderstandings between collaborators not mentioned here will be subject to discussion by the PB.

Publishing single centre data (own data)

Collaborators may use PAIN OUT data collected from patients in their center for the purpose of preparing an abstract, poster, oral presentation or manuscript.

- Collaborators will be responsible for carrying out analysis of their own data.
- We strongly recommend that authors send a proposal for any manuscript they plan to the Publication Board for review. This review aims to assess for overlap with other proposals, that might result in possible duplication of studies, hindering the chances of publication.**
- Authors will send a copy of the work to the PB before it is submitted for publication.
- The proposal will then be posted in the Publication Board area of the PAIN OUT project, as 'accepted'.

Screenshots from the project's benchmark server can be included in posters and oral presentations. They should not be used for public relations of a particular ward or hospital.

Disclosures

When applicable, authors of publications and presentations will acknowledge that the research leading to their results was supported by funding from the respective companies/institutions.

Acknowledging EU funding All publications which contain data related to PAIN OUT should include the following acknowledgement: "The research leading to these results has received funding from the European Community's Seventh Framework Programme FP7/2007-2013 under Grant Agreement No. 223590". Posters must also include the project's and EU logos (obtainable from the PAIN OUT coordination team).

References

- Battisti WP et al; International Society for Medical Publication Professionals. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med.* 2015 Sep 15;163(6):461-4.
- International Committee of Medical Journal Editors, **Recommendations** for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals. www.icmje.org

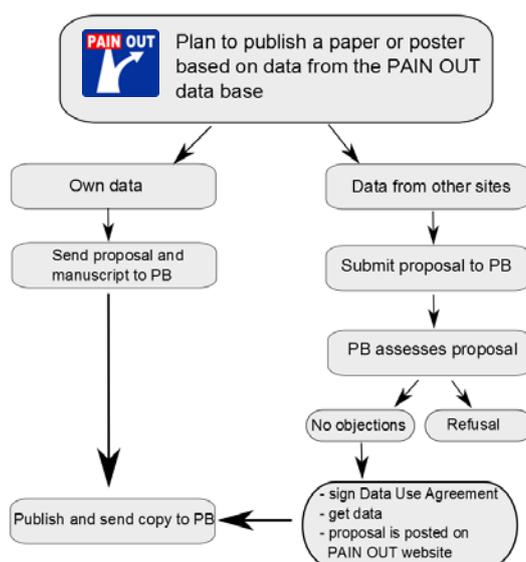


Fig. 1: General Scheme for Secondary Publications



Appendix 1–Template for submitting a proposal for publication within the PAIN OUT project

HOSPITAL / Address
 DEPARTMENT
 DATE
 NAME PERSON SUBMITTING

Title (working version):
Research question:
Statistical methods for analysis:
Target journal:
Time Schedule:
Lead authors:

Please fill in below the type of variable you would like to analyse (add as many lines as is necessary):

Prospective authors will not receive the complete dataset; they should outline the surgical speciality (ies) they wish to receive and / or data for specific procedures .

Research question to assess	Type of variable	Name of variable
	Demographics	
	Medical history	
	Pre-medication	
	Medical procedure(s)	
	Intra-operative	
	Recovery	
	Ward	
	Outcomes	

Once filled in, the form can be scanned and sent to Claudia.Weinmann@med.uni-jena.de



Appendix 2

PAIN OUT Data Use Agreement

This agreement is entered into by and between University Hospital Jena ('UKJ'), acting on behalf of the PAIN OUT project and the Recipient ('Recipient') named on Schedule 1 (attached hereto and by this reference incorporated herein) as of the Effective Date noted on Schedule 1.

- A. After formal approval of the PAIN OUT publication board, UKJ is providing certain anonymized raw data collected within the PAIN OUT project to Recipient in the form of a Limited Data Set for the research purpose(s) identified in Schedule 1.
- B. In connection with the provision of these anonymized raw data, UKJ is required to obtain assurances from Recipient that Recipient will only use or disclose the data according to this Data Use Agreement.

THEREFORE, the parties agree as follows:

1. **Term:** This Agreement shall commence on the Effective date and continue until terminated in accordance with Schedule 1
2. **Recipient's obligations.** Recipient shall:
 - a. Comply with all applicable laws and regulations relating to maintenance of patient data, safeguarding of the confidentiality and the use and disclosure of patient data.
 - b. Use and disclose the data only for the purpose(s) identified in Schedule 1.
 - c. Use appropriate safeguards to prevent the use and disclosure of the data other than for use or disclosure expressly permitted by this Agreement.
 - d. Never make the data available to third parties.
 - e. Immediately report to UKJ any use or disclosure of the data other than as expressly allowed by this Agreement.
 - f. Provide information on the way the data have been used on demand of UKJ.
 - g. Ensure that its employees and representatives comply with the terms and conditions of this Agreement.
 - h. Not identify or attempt to identify the information contained in the data set.
 - i. Indemnify, defend and hold UKJ harmless from all costs and expenses (including attorney fees) for any claims that relate to a release of these data or that relate to a breach of Recipient's obligations.
 - j. Destroy the data provided by UKJ after termination of this agreement and send a written statement of destruction to UKJ within 10 days.
3. **Termination:** UKJ may terminate this Agreement and any disclosure of data upon 10 days notice to Recipient if Recipient violates or breaches any condition of this Agreement. UKJ may terminate this Agreement without cause upon 30 days written notice. Upon termination, Recipient shall promptly destroy the data and send a written statement of destruction to UKJ. If Recipient terminates this agreement, Recipient agrees to promptly destroy all data provided by UKJ.
4. **Governing Law and Venue:** This Agreement shall be governed by the laws of Germany. Venue for any claim, action or suit shall be Jena, Germany.

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the Effective Date:

University Hospital Jena:
By: _____

Recipient:
By: _____

(signature) _____
Title: _____
Date: _____

(signature) _____
Title: _____
Date: _____



Improvement in postoperative PAIN OUTcome

Schedule 1

1. Effective Date:

2. Name of UKJ Department/Person releasing the data: Prof. Dr. Winfried Meissner, Department of Anaesthesiology and Intensive Care Medicine, on behalf of the PAIN OUT project.

3. Name of Recipient of the data:

4. Purpose of data disclosure (description of research purpose(s)):

5. The recipient of the data listed in #3 is permitted to use and disclose the data for the following purposes:

6. Only the following individuals are permitted to use and disclose the data:

7. Termination:

Once filled in, the form can be scanned and emailed to Claudia.Weinmann@med.uni-jena.de or pain-out@med.uni-jena.de