



Worldwide Assessment of Separation of Patients From ventilatory assistance (WEAN SAFE STUDY)

OPEN WEAN SAFE: Data Access, Publication and Authorship Policy

A. Introduction

The WEAN SAFE study aimed at describing the weaning process in detail, characterizing different approaches used by physicians regarding weaning from mechanical ventilation, and the impact of delayed and failed weaning from ventilation, in patients requiring at least two days of invasive ventilation.

The study was partially funded by the European Society of Intensive Care Medicine and by the European Respiratory Society, and performed by a consortium of investigators from 481 ICUs across 50 countries.

The primary paper was published recently in The Lancet Respiratory Medicine. In addition, several pre-defined secondary analyses will be conducted as outlined in the study protocol.

All the data were collected on a voluntary basis by the investigators, under the agreement that all the WEAN SAFE investigators would have had the opportunity to propose additional studies requiring data analyses not covered by the original manuscript.

To this end, the WEAN SAFE Executive Committee has defined this policy for data access, publication and authorship as described below.

The objectives of this policy are:

- To allow WEAN SAFE investigators to propose secondary analyses of the database, avoiding overlaps and duplicate studies.
- To assure timely dissemination of WEAN SAFE Investigators findings to the scientific community.
- To maintain high scientific standards for published material.
- To assure equitable investigator participation and attribution of authorship in presentations and publications.
- To ensure appropriate credit is given to WEAN SAFE Investigators and supporting societies on publications
- To prevent publications that:
 - a. are factually or conceptually inaccurate
 - b. publish data that can be tracked to centre level without the explicit permission of those centres.
 - c. prematurely release data which might subsequently preclude publication of results in high quality peer reviewed journals
 - d. are redundant

Executive committee for OPEN WEAN SAFE initiative

The WEAN SAFE Executive Committee (comprising T Pham, L Heunks, G Bellani, L Brochard and J Laffey) will review OPEN WEAN SAFE proposals and aim to optimize the coordination of different studies.



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B. Proposals for Secondary Publications arising from WEAN SAFE Study

1. The Executive committee encourages WEAN SAFE investigators to submit suggestions for additional analyses that would result in secondary publications and presentations.
2. A formal invitation to submit proposals will be issued in three steps. Members of the WEAN SAFE Executive and Steering committees and National Coordinators will have a period of four weeks following publication of this call on the ESICM website to submit their proposals. After these 4 weeks, in step 2, all the WEAN SAFE investigators will have the possibility to submit proposals. At a later stage, in step 3, a general call will be issued to the research community where all researchers can make study proposals.
3. Thereafter, general calls for proposals will be issued periodically (2-3 times a year). Each call will have a deadline. The WEAN SAFE Executive committee will meet after each deadline to evaluate and rank proposals and give feedback to the authors of the proposals.
4. A proposal form is available on the ESICM website, and should be used for all such proposals, otherwise submissions will not be evaluated.
5. These proposals will be forwarded to the Executive Committee for approval. Proposals from WEAN SAFE investigators (i.e., site investigators and national coordinators) will take priority. We anticipate that all requests for scientifically sound sub-analyses will be approved by the Executive Committee.
6. Investigators who received any financial support (academic or industrial), specifically directed to the investigation proposed, should disclose this in the request form.
7. Evaluation of the proposals will consist in a two-steps process.
8. The first step is aimed at evaluating the general soundness of the proposal and the potential conflict/overlap with other proposals. In the case that data is insufficient to answer a particular question, investigators might be asked to refine their hypothesis accordingly. For duplicate or overlapping requests, the Executive Committee will attempt to facilitate the collaboration between the proponents; if this cannot be achieved, the first investigator who submits the request will have priority.
9. If the proposal is approved at the first stage, proponents will be requested to submit a detailed statistical analysis plan, which also will undergo evaluation from the Executive Committee.
10. After Executive Committee approval, final proposals will be circulated to the WEAN SAFE steering committee with a tacit approval rule.
11. Investigators should normally expect a response on their proposal within four weeks.
12. The titles of approved (and hence undergoing) proposals will be posted on the WEAN SAFE page of the ESICM website, to facilitate further applicants in avoiding overlaps.

C. Statistical Analysis and Manuscript preparation

1. For the purposes of maintaining data integrity, and because of restrictions placed by institutional ethics committees on the use of their centre data, none of the “raw” data can be disclosed directly to the investigators.
2. A dummy dataset will be provided that has the exact same structure as the real dataset. This can be used by study teams to create their statistical analysis in ‘R’ which can then be run by the WEAN SAFE statisticians and the data provided to the study team. ***Study teams who have the statistical expertise to work with a dummy dataset will be prioritized*** as this will greatly expedite the analysis.



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3. Where study teams are unable to work with a dummy dataset, the statistical analysis will be fully performed by statisticians appointed by the Executive Committee. This will likely take longer, given the additional statistician time required, and this may need to be resourced by the study team.
4. The Executive Committee must review all manuscripts prior to submission for publication. This added layer of peer review should increase the quality of the sub-analyses and will serve as a final check on duplicate reports
5. For all manuscripts describing secondary analyses, the finalization of the (a) study hypothesis; (b) study design; (c) statistical analysis plan; and (d) data interpretation; as well as the overall handling of the manuscript will be managed by the Executive Committee PLUS the investigators that submitted the relevant proposal that was approved by the OLS-EC.
6. Investigators are not allowed to disclose data to third parties before manuscript publication

D. Rules of authorship

1. Attribution of authorship is expected to vary by type of publication or presentations. Procedures for each are detailed below.
2. Where substudies are approved the Writing committee will consist of the members proposed by the investigators, with additions by the Executive Committee as required. Where multiple similar proposals are received, the WEAN SAFE Executive Committee will work to achieve a consensus on the composition of the Writing committee for the proposal. Where consensus is not achieved, the Executive Committee will be the ultimate arbiter in determining the composition of the Writing Committee for approved substudies.
3. The first named author will usually be the person that led the sub-study and/or proposed the additional analysis of the WEAN SAFE database.
4. In all cases where WEAN SAFE data or other resources are utilized, the term “WEAN SAFE Investigators” must be included at the end of the list of authors on the manuscript.
5. The list of WEAN SAFE investigators must be included as collaborating Authors. This list will be provided by the Executive Committee.

In all cases where WEAN SAFE data or other resources are utilized, the funding support from ESICM and from ERS must also be acknowledged.

E. Submission Policy

Submission to the ESICM journal “Intensive Care Medicine” or the ERS journal ‘European Respiratory Journal’ is encouraged.

In the case of submission/publication fees, these must be covered by the PI of the proposals or by one of the members of the writing committee.

F. Abstracts

Abstracts generated by the Writing Committees appointed as above described should reflect the topic of the original proposals (and hence of the manuscript being drafted). All abstracts will be reviewed by the Executive Committee within 2 weeks of receipt.

The approved, edited, abstract must be circulated to all co-authors for comment prior to submission.

Co-authors comments are expected to be sent to the Writing Committee chairman within two weeks.



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Because of limited space in abstracts, the chairman of the writing committee (or his/her designee) will be the first author, followed by "The WEAN SAFE Investigators". The same person will also act as presenter during the conference.

In the case of submission fees, these will have to be covered by the PI of the proposals or by one of the members of the writing committee as well as the expenses for the conference abstract presentation