Analytical Plan for Self-assessment of an end of life care training program for respiratory care practitioners

DOCUMENT: SAP-2022-015-JL-v01

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2022-04-18

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Analytical Plan for Self-assessment of an end of life care training program for respiratory care practitioners

Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

N/A

2 CONTEXT

2.1 Objectives

Evaluate satisfaction and pre/post perception of knowledge and confidence of respiratory care students after an end of life care training program.

2.2 Hypotheses

Students are satisfied with their learning after the training program.

2.3 Study design

Cross-sectional design, single arm survey to assess efficacy of the training program.

3 DATA

3.1 Raw data

Survey data was received in a table, where the survey mechanism segregated each possible answer to the Likert scale questions as separate columns. Each of these columns had two answers for the assessment of the before and after satisfaction with the training program. In order to perform the pre/post comparison of these responses we created two columns per question, one for each time point being assessed. This was achieved by searching for the keywords "before" and "after" in each column and

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matching those results to the new before/after columns created. This procedure effectively counts each participant answer only once, thus creating one categorical variable for each question at each time (see observations). It was applied to the following four pre/post questions:

- **q5:** "5. I feel that I am knowledgeable in end-of-life care services required for the respiratory care practitioner"
- **q6:** "6. I would be comfortable communicating with dying patients during end-of-life care"
- **q7:** "7. I would be comfortable communicating with grieving family members during end-of-life care"
- **q8:** "8. I feel that I am adequately prepared for how to participate in end-of-life care needs for a dying patient?"

The original data base had 52 variables collected on 79 observations. This includes identifier columns like name, location, time when the survey was responded and agreement to participate in the study, which were excluded from the analytical dataset. The survey also included a couple of open text questions intended for a qualitative analysis, which were also excluded from this analysis.

3.2 Analytical dataset

After the cleaning process 21 variables were included in the analysis. The total number of observations excluded due to incompleteness and exclusion criteria will be reported in the analysis. Table 1 shows the structure of the analytical dataset.

Table 1 *Analytical dataset structure after variable selection and cleaning.*

id	q1	q2	q3	q4	q5_before	q5_after	q6_before	q6_after	q7_before	q7_after	q8_before	q8_after	q9	q10	q11	q12	q13	q14	q15	q17
1																				
2																				
3																				
…																				
N																				

All variables in the analytical set were labeled according to the raw data provided and values were labeled according to the data dictionary for the preparation of production-quality results tables and figures.

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4   STUDY PARAMETERS

4.1   Inclusion and exclusion criteria

Incomplete surveys will be excluded from the analysis. These will be identified by the `finished` column present in the raw data.

4.2   Exposures

All survey respondents were exposed to the training program in this single arm pre/post evaluation.

4.3   Outcomes

Specification of outcome measures (Zarin, 2011):

1.   (Domain) Satisfaction
2.   (Specific measurement) Self-assessed satisfaction on a 5-point Likert scale
3.   (Specific metric) Change from baseline
4.   (Method of aggregation) Proportion of each possible answer on the 5-point Likert scale

Primary outcome

Proportion of survey respondents that agree with the satisfaction questions on the training program efficacy in their end of life respiratory care practice.

4.4   Covariates

N/A

5   STATISTICAL METHODS

5.1   Statistical analyses

5.1.1   Descriptive analyses

The raw answers for each question will be described as   counts and proportions (%). The distributions of participants' answers will be summarized in tables and visualized in exploratory plots.

5.1.2   Inferential analyses

All comparisons between pre and post training agreement with the questions will be performed as univariate analyses. Answers will be treated as continuous variables and

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the paired comparisons for survey participants between the two time points with the Wilcoxon signed rank test.

5.1.3 Statistical modeling

N/A

5.1.4 Missing data

No missing data imputation will be performed. All evaluations will be performed as complete case analyses.

5.2   Significance and Confidence Intervals

All analyses will be performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed will be two-tailed.

5.3   Study size and Power

N/A

5.4   Statistical packages

This analysis will be performed using statistical software R version 4.1.3.

6   OBSERVATIONS AND LIMITATIONS

Multiple answers per question

The survey was designed to allow participants to choose multiple answers per question. It would theoretically be possible for a participant to answer both "Yes" and "No" to the same question, in which case the survey mechanism would create additional columns to handle this data structure.

This was indeed what happened to the main questions for the scope of this analysis, that assessed the before and after satisfaction with the training program (questions 5 through 8). In order for this analysis to be performed a categorical variable was created (see section Data) thus effectively selecting only one answer per question, of a theoretical maximum of five. It is not clear how this choice could bias the analysis results, if several participants gave multiple answers to the same question.

Pre and post assessments at a single time point

This survey assessed the satisfaction of how the participant perceive their knowledge and confidence in offer end of life care, measured on a Likert scale. The self-assessment

was measured separately for two time points (before the training and after the training took place), but both measurements were made at the end of the program.

This could bias the self-assessment of the pre-training answers towards lower rates, thus increasing the perceived difference participants have of their growth due to the program. This might happen since the participants were not surveyed at two different time points, making it hard to compare their self-assessment of knowledge and confidence. One must interpret these pre/post differences with caution, taking into account the design of the study.

7   REFERENCES
- **SAR-2022-015-JL-v01** – Self-assessment of an end of life care training program for respiratory care practitioners
- Zarin DA, et al. The ClinicalTrials.gov results database – update and key issues. N Engl J Med 2011;364:852-60 (https://doi.org/10.1056/NEJMsa1012065).
- Gamble C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017;318(23):2337–2343 (https://doi.org/10.1001/jama.2017.18556).

8   APPENDIX

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

8.1 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2022-015-JL/

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