

1 **The impact of a 22-month multi-step implementation programme**
2 **on speaking-up behaviour in an academic anaesthesia department**
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4 Fabio Walther ^{1,*}, Carl Schick ^{1,*}, David Schwappach ^{2,3}, Evgeniya Kornilov ⁴, Sharon Orbach-
5 Zinger ⁴, Daniel Katz ⁵, Michael Heesen ¹

6
7 ¹Department of Anaesthesiology, Kantonsspital Baden, Baden, Switzerland

8 ²Swiss Patient Safety Foundation, Zürich, Switzerland

9 ³Institute of Social and Preventive Medicine, University of Bern, Switzerland

10 ⁴Department of Anaesthesia, Beilinson Hospital, Tel Aviv University, Tel Aviv, Israel

11 ⁵Department of Anaesthesiology, Perioperative and Pain Medicine, Mount Sinai, New York,
12 USA

13 *These authors contributed equally to this work and share first authorship: F.W. and C.S.

14
15 Corresponding Author

16 Fabio Walther

17 Im Ergel 1

18 5405 Baden

19 fabio.walther@ksb.ch

20 0041 76 671 01 61

21 Running title: the effect of a 22-Month speaking-up programme

22 Abstract

23 Background

24 Speaking-up is a method of assertive communication, which increases patient safety, but of-
25 ten encounters barriers. Numerous studies describe programmes introducing speaking-up
26 with varying success; the common denominator seems to be the need for a multimodal and
27 sustained approach in order to achieve the required change in behaviour and culture for
28 safer healthcare.

29 Methods

30 Before implementing a 22-month multistep programme for establishing and strengthening
31 speaking-up at our institution, we assessed perceived safety culture using the “Safety Atti-
32 tudes Questionnaire”. After programme completion, participants completed parts of the
33 same “Safety Attitudes Questionnaire” relevant to speaking-up, and pre- and post-results
34 were compared. Additionally, levels of speaking-up and assertive communication were com-
35 pared with a Swiss benchmark using results from the “Speaking-up About Patient Safety
36 Questionnaire”.

37 Results

38 “Safety Attitudes Questionnaire” scores were significantly higher after programme comple-
39 tion in two of three answered questions (5.0 (4.0, 5.0) versus 4.0 (4.0, 5.0) $p=0.0002$ and 5.0
40 (4.0, 5.0) versus 4.0 (4.0, 4.0) $p=0.002$, Median (1st quartile, 3rd quartile)) ($n = 34$). Our com-
41 posite score on the “Speaking-Up About Patient Safety Questionnaire” was significantly
42 higher (5.9 ± 0.7 versus 5.2 ± 1.0 , mean \pm standard deviation, $p < 0.001$) than the benchmark
43 ($n = 65$).

44 **Conclusion**

45 A long-term multimodal programme for speaking-up was successfully implemented. Attitude
46 and climate towards safety generally improved and post-programme perceived levels of as-
47 sertive communication and speaking-up were higher than the benchmark. These results sup-
48 port current opinion that multimodal programmes and continued effort are required, but
49 that speaking-up can indeed be strengthened.

50 **Keywords**

51 Speaking-Up, psychological safety, high-fidelity simulation, online learning

52 Introduction

53 Speaking-up is a method of assertive communication by which concerns, such as threats to
54 patient safety or the presence of unsafe conditions, are stated with persistence until there is
55 a clear resolution.^{1, 2, 3} According to the Joint Commission's sentinel event data from 2015,
56 the failure to speak up was one of the top three root causes for adverse events in the peri-
57 operative period.⁴ Withholding voice despite safety concerns is a common behaviour among
58 health care professionals. A Swiss multicentre study reported that 19%–39% of health-care
59 workers had chosen to withhold voice within the past four weeks.⁵ Several barriers for
60 speaking-up have been identified in the perioperative setting, including perceived ineffec-
61 tiveness, presence of patients and authority gradients.^{1, 6}

62 Research on the implementation of speaking-up has mainly focused on single groups, includ-
63 ing nursing students,⁷ medical students,⁸ and residents.^{9, 10} In general, implementation of
64 speaking-up has demonstrated varying success,^{11, 12} but common themes include: necessity
65 for an implementation programme involving all members of staff, education to support a
66 transformation in organisational culture,¹³ and addressing norms and communication behav-
67 iours.¹⁴ In short, strengthening a culture of speaking-up is an ongoing challenge¹⁵ but also
68 crucial to increasing patient safety.

69 In order to establish and strengthen speaking-up in our department, we developed and em-
70 ployed a 22-month multi-step implementation programme. To measure the effect of the
71 programme, we compared perceptions of speaking-up before and after the intervention us-
72 ing elements from the "Safety Attitudes Questionnaire", a validated questionnaire for per-
73 ceptions of patient safety related attitudes, as our primary outcome. As a further measurement,

74 and secondary outcome, we compared post-intervention levels of speaking-up and assertive
75 communication with comparable Swiss institutions using the “Speaking-Up About Patient
76 Safety Questionnaire”.

77 **Methods:**

78 **Study institution and population:**

79 The study was performed in the Cantonal Hospital of Baden, a 382 bed teaching hospital of
80 Zurich University, which annually treats more than 20`000 inpatients and more than 170`000
81 outpatients. All staff members of the department of anaesthesia, i.e. nurse and physician
82 anaesthetists (both residents and consultants) employed at any time during the 22 months
83 were exposed to the implementation programme. The requirement for approval of our
84 study, as well as for written consent, was waived by the ethical committee “Nordwest-
85 schweiz” as well as by our institutional legal board. Participants gave verbal consent. Mate-
86 rial was de-identified before any analysis, and destroyed hereafter in conformance with legal
87 requirements.

88 A total of 117 staff members participated in the implementation programme at some time
89 during the 22 months, but due to staff fluctuations, availability, and study requirements, the
90 number of available participants varied over time. Details are presented on the timeline of
91 the project in Figure 1.

92

93 Fig. 1: the implementation programme – of 177 members of staff present at some time during the in-
94 tervention, 57 participated in the baseline survey, of which 34 completed the repeat survey, providing
95 data for the primary objective. Independent of participation in the baseline survey, 65 members of
96 staff completed the programme and were available for the Speaking-Up About Patient Safety survey,
97 the secondary outcome.

98

99 **Baseline survey**

100 Prior to implementing the programme, the 57 current members of staff available completed
101 the German language version of the Safety Attitudes Questionnaire. This questionnaire is a
102 validated tool to assess^{16, 17} healthcare workers' perceptions of patient safety related atti-
103 tudes in various clinical areas. Depending on the version, it is comprised of 30 – 60 items
104 measured on a 5-point Likert scale covering six aspects of the safety climate: teamwork cli-
105 mate, job satisfaction, safety climate including perception of speaking-up, stress recognition,
106 working condition and perception of management. The German translation was recently val-
107 idated¹⁸ and successfully tested in 10 Swiss hospitals¹⁹ and transcribed to the Survey Mon-
108 key © online platform for our survey of baseline values.

109 **The Implementation Programme**

110 Following the baseline survey, the multimodal implementation program was initiated in Au-
111 gust 2019, and incorporated into the entire anaesthesia department over a course of 22
112 Months. It consisted of various elements including an awareness campaign, an on-line
113 course, simulation based team trainings, and explicit invitation to speak-up incorporated
114 into daily practice.

115 To begin the programme, all current staff members were required to participate in the
116 online course developed using the hospital's native e-learning software, © easylearn
117 schweiz ag, comprised of three components. Firstly, background knowledge and the ra-

118 rationale for speaking-up were presented together with instructions including the two-chal-
119 lenge rule,²⁰ and providing coaching in advocacy-inquiry with specific examples. The second
120 element was a video featuring the department head as the recipient of speaking-up. Finally,
121 there was a multiple choice exam testing participant's knowledge on rationale and barriers
122 for speaking-up, the effect of the authority gradient, and identification of the correct word-
123 ing of speaking-up using crisp advocacy-inquiry in various described situations. This exam
124 was graded, and a pass was required. One year later, members of staff were again exposed
125 to the same mandatory online course module as a refresher.

126 Complementing the teaching, we performed three high-fidelity in-situ simulations with vari-
127 ations of opportunity for speaking-up throughout the implementation programme, to which
128 we assigned as many staff members as rostering allowed during the pandemic:

- 129 • interdisciplinary team-training for obstetric anaesthesia staff with scripted opportunity
130 for speaking-up during the scenarios (40 participants from our department) in December
131 2019
- 132 • anaesthesia induction sequence with scripted speaking-up situations with an acting in-
133 structor (75 participants) in October 2020,
- 134 • interdisciplinary team-training sessions for same-day surgery teams, and obstetric anaes-
135 thesia teams, with special focus on speaking-up in debriefings (29 participants from our
136 department) in April 2021

137 Scenarios and teaching elements were developed and tested prior to study-use by the Au-
138 thor C.S., a trained instructor for medical simulation with experience developing standard-
139 ised scenarios for measurement and research,²¹ then refined by the authors C.S., F.W. and
140 M.H. using a modified Delphi approach, and finally tested by fellow simulation instructors.

141 Additionally, the programme was accompanied by a continuous awareness campaign includ-
142 ing various lectures and workshops reiterating the topics of the online course (background
143 knowledge and the rationale for speaking-up, instructions and suggestions for providing
144 speaking-up, and coaching in advocacy-inquiry with specific examples), and an interview
145 with the head of the department in the hospital newspaper, in which he discussed hierarchy
146 and status issues, introduced the concept of, and called for, speaking-up.

147 Finally, as of January 2020, we incorporated speaking-up into our daily clinical practice by
148 augmenting the pre-induction checklist and team-briefing with the request to perform
149 speaking-up made by the highest-ranked team member. This action served a dual purpose –
150 as an ongoing reminder of leadership commitment to speaking-up, and a tool to reduce the
151 barriers of hierarchy by the mechanism of leader inclusiveness – words and deeds by leaders
152 that invite and appreciate others’ contributions which can take nature off its course, helping
153 to overcome status’ inhibiting effects on psychological safety.²²

154 Primary Outcome – Pre-Post comparison using the “Safety Attitudes Questionnaire”

155 For our primary outcome, we interviewed all current members of staff who completed the
156 whole implementation programme and had participated in the baseline survey (n = 34) using

157 the following three questions from the “Safety Attitudes Questionnaire” used for the base-
158 line survey, which specifically focus on assertive communication and speaking-up, after the
159 implementation period of 22 months and compared scores:

- 160 • *In this clinical area, it is difficult to speak up if I perceive a problem with patient care.*
- 161 • *In this clinical area, it is difficult to discuss errors.*
- 162 • *I am encouraged by my colleagues to report any patient safety concerns I may have.*

163 Both cohorts contained the same participants and results were compared unpaired.

164 [Secondary Outcome – comparison of results from our institution with the benchmark of](#)
165 [comparable Swiss institutions using the “Speaking-Up About Patient Safety Questionnaire”.](#)²³
166 65 members of staff participating in the implementation programme from the beginning and
167 available at the time of the survey completed the Speaking-Up about Patient Safety Ques-
168 tionnaire, a validated questionnaire developed by the Swiss Patient Safety Foundation focus-
169 sing on speaking-up and assertive behaviour among healthcare staff. Specifically, the ques-
170 tionnaire assesses the two theoretical constructs of speaking-up and withholding voice,
171 while covering three speaking-up climate related subscales: psychological safety for speak-
172 ing-up, encouraging environment, and resignation. The Questionnaire has been used in 22
173 Swiss hospitals, and in 5 comparable departments, which allows valuable cross-hospital
174 comparisons of speaking-up behaviours and climate.

175 Statistical analysis

176 Results for the primary and the secondary outcome were examined by inspection of the his-
177 tograms. Negatively worded items were reversed before statistics were performed. Two-
178 sided p-values < 0.05 were considered statistically significant. All statistical analyses were
179 conducted using R version 4.0.2²⁴

180 To compare the pre- and post-implementation results of the three relevant questions on the
181 Safety Attitudes Questionnaire (1^o outcome), a Mann-Whitney U-Test for non-paired sam-
182 ples was performed. Due to the small sample size and lack of normal distribution, we pre-
183 sent the median, and 1st and 3rd quartile.

184 Concerning the secondary outcome, we compared the results of the “Speaking-Up About Pa-
185 tient Safety Questionnaire” to the benchmark values using Welch's t-test for unequal vari-
186 ances; here, we report the mean and SD according to previous analyses.²³

187 Results

188 Primary outcome

189 Of the 57 members of staff initially completing the pre-implementation Safety Attitudes
190 Questionnaire, 34 (59.6%) completed the whole implementation programme and were also
191 available for the post-implementation survey with the three relevant questions from the
192 questionnaire.

193 Scores after implementation were significantly higher in 2 of 3 questions surveyed and did
194 not change significantly in the third question (Table 1).

195 Table 1: comparison of median (1st Q, 3rd Q) responses to Safety Attitude Questionnaire items pre- and
196 post-implementation.

197

198 Secondary outcome

199 A total of 65 members of staff which had completed the implementation programme also
200 completed the Speaking-Up About Patient Safety Questionnaire. Safety concerns were com-
201 mon among survey participants. The majority reported at least one patient safety concern
202 during the past four weeks (92%). At least one episode of speaking-up during the past four
203 weeks was reported by 94%. At least one episode of “withholding voice” was reported by
204 58%. The barriers reported by respondents as hindering them to voice their concerns were
205 reaction of the actor not predictable (35%), presence of patients or relatives (34%), ineffec-
206 tiveness of speaking-up (31%), unclear risk for the patient (29%), difficulty finding the right
207 tone (12%) and fear of negative reactions (8%).

208 Overall responses to the climate survey items are reported in Table 2. Results obtained in
209 this study were higher when compared to the Swiss perioperative care sample.⁶ Respon-
210 dants in our hospital reported higher levels of psychological safety, a more positive encour-
211 aging environment, and described less resignation towards speaking-up.

212 Table 2: comparison of mean (SD) responses to climate survey items for our department and the Swiss
213 comparison.

214

215 Discussion

216 Results

217 We found that the 22 month implementation programme was associated with higher levels
218 of self-reported speaking-up behaviour, as evidenced by a significant improvement in two of
219 three elements on the post-implementation Safety Attitudes Questionnaire items addressing

220 assertive communication and speaking-up, and higher over-all scores in the climate survey
221 as compared to the benchmark of similar healthcare institutions in Switzerland.

222 Although our study did not investigate the effects of each separate intervention within the
223 programme, evidence does suggest that leader inclusiveness and leadership support is criti-
224 cal – as such, we feel that our head of department providing interviews, lectures, and a
225 scripted video inviting to speaking-up was essential for the programme’s success and pa-
226 tient-safety climate in our department.

227 Although there was an improvement in 2 out of 3 responses on the Safety Attitudes Ques-
228 tionnaire, the survey question “I am encouraged by my colleagues to report any patient
229 safety concerns I may have” did not show any improvement post implementation. We be-
230 lieve this might be because of the relatively high baseline value (4.0 on a 5-point scale), and
231 the fact that our implementation programme did not explicitly focus on peer support as
232 much as the more prominent issues of hierarchy, leadership and empowerment. Also, the
233 request to perform speaking-up expressed by the highest ranked team member at every in-
234 duction might have made encouragement by other team members seem less important.
235 However, this evidence seems to show that strengthening of peer support to do the right
236 thing might indeed need more focus in consecutive programmes.

237 Although the higher over-all scores in the Speaking-up About Patient Safety Questionnaire as
238 compared to the benchmark of similar healthcare institutions in Switzerland suggest a posi-
239 tive effect of our implementation programme, some results are sobering, albeit not unex-
240 pected. Although most respondents reported at least one patient safety concern during the

241 past four weeks, over half reported withholding voice within the same period - this is a stark
242 reminder of the fact that even an intervention of our dimension is only one step on the road
243 to patient safety. Reported barriers (unpredictable reaction of recipient of speaking-up,
244 presence of patients or relatives, assumed or experienced ineffectiveness of speaking-up, an
245 unclear risk for the patient, difficulty finding the right tone and fear of negative reactions)
246 persist, and provide a road map for further interventions. As we only implemented our pro-
247 gramme in the department of anaesthesia, we must consider one barrier, the assumed or
248 experienced ineffectiveness, in context of interdisciplinary communication in particular: if
249 the culture of patient safety and leadership support for speaking-up is less well established
250 in a department closely interconnected such as surgery, there is a limit to the benefit for pa-
251 tient safety which can be achieved by improvements in one department only.

252 [Strengths of our study:](#)

253 To our knowledge, our study is one of the first to detail a longitudinal and multifaceted im-
254 plementation programme involving all levels of staff and leadership, addressing speaking-up
255 and voice behaviour, and providing objective measures of its success. A further advantage is
256 our comparison of scores to a national benchmark.

257 [Limitations of our study:](#)

258 Our study is limited by its small size and relatively small response rate. Due to the require-
259 ment that study participants completed the whole implementation programme and staff
260 fluctuation over the 22 months, overall numbers were smaller than expected. Additionally,
261 the prominence of leadership support in “safe behaviour” makes a Hawthorne effect highly
262 likely.

263 Furthermore, at the time of the study we did not have a structured reporting instrument for
264 near misses and adverse events in place apart from the critical incident reporting system,
265 which due to legal restrictions in Switzerland cannot be considered a representative data-
266 base. Improvements in reporting are a logical next step for the implementation programme.

267 Another possible limitation is that this study was a single centre study in one department
268 and cultural region; it is unclear in how far results are reproducible in another department,
269 institution, or even country with different norms and cultures. Indeed, a department of an-
270 aesthesia with a traditionally shallow hierarchy in Switzerland (being a country with low
271 power distance index but relatively high scores on indices for individualism, masculinity, and
272 uncertainty-avoidance according to Hofstede's cultural dimensions) probably requires em-
273 phasis on different elements of a multimodal approach as would a different department or
274 population in another cultural setting. Due to this limitation, we feel that a rigorous investi-
275 gation into perceived barriers before implementing such a program – as we performed using
276 the Safety Attitudes Questionnaire – can provide valuable guidance to address these differ-
277 ences.

278 Conclusion

279 A long term, inclusive and multi-step programme for establishing speaking-up was success-
280 fully implemented at our institution. Attitude and climate towards safety in our department
281 improved after implementation according to “SAQ”-scores; the “Speaking-Up About Patient
282 Safety Questionnaire” respondents at our institution reported higher levels of psychological
283 safety, a more positive encouraging environment, and described less resignation towards
284 speaking-up, as in comparable Swiss institutions. These results seem to support current

285 opinion that, although a multimodal programme and continued effort are required to assist
286 the change in culture and behaviour towards safer healthcare, increases in levels of speak-
287 ing-up can indeed be achieved.

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292 Conflicts of interests

293 All the authors report no conflicts of interest.

294 Authors contributions

295 FW: Designed the study, performed the analyses, interpreted the data, drafted the manu-
296 script.

297 CS: Designed the study, performed the analyses, interpreted the data, drafted the manu-
298 script.

299 DS: Designed the study, performed the analyses, interpreted the data, drafted the manu-
300 script.

301 EK: Performed the analyses, interpreted the data.

302 SOZ: Designed the study, drafted the manuscript.

303 DK: Designed the study, interpreted the data, drafted the manuscript.

304 MH: Designed the study, performed the analyses, interpreted the data, drafted the manu-
305 script.

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380 **Legend**

381 Fig. 1: the implementation programme – of 177 members of staff present at some time dur-
382 ing the intervention, 57 participated in the baseline survey, of which 34 completed the re-
383 peat survey, providing data for the primary objective. Independent of participation in the
384 baseline survey, 65 members of staff completed the programme and were available for the
385 Speaking Up About Patient Safety survey, the secondary outcome.

386 Table 1: comparison of median (1st Q, 3rd Q) responses to Safety Attitude Questionnaire
387 items pre- and post-implementation.

388 Table 2: comparison of mean (SD) responses to climate survey items for our department and
389 the Swiss comparison.

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| Safety Attitudes Questionnaire (measures on a 6-point scale) | median (1 st quartile, 3 rd quartile) | | p value |
|---|---|--------------------|---------|
| | (n=34) | pre-implementation | |
| In this clinical area, it is difficult to speak up if I perceive a problem with patient care. | 4.0 (4.0, 4.75) | 5.0 (4.0, 5.0) | 0.0002 |
| In this clinical area, it is difficult to discuss errors. | 4.0 (4.0, 4.0) | 5.0 (4.0, 5.0) | 0.0022 |
| I am encouraged by my colleagues to report any patient safety concerns I may have. | 4.0 (3.0, 4.0) | 4.0 (3.0, 5.0) | 0.7220 |

397 Table 1: comparison of median (1st Q, 3rd Q) responses to Safety Attitude Questionnaire items pre- and
398 post-implementation.

399

| Items and scales (measure on a 7-point Likert scale) | mean (SD) | | p value |
|---|--------------------|---|---------|
| | This sample (n=65) | Swiss perioperative care sample (n=360) | |
| <i>Psychological Safety for Speaking up, mean scale score</i> | 6.2 (0.6) | 5.5 (1.1) | <0.001 |
| I can rely on my colleagues (doctors and/or nurses), whenever I encounter difficulties in my work. | 6.4 (0.6) | 5.6 (1.4) | <0.001 |
| I can rely on the shift supervisor (person in charge of a shift) whenever I encounter difficulties in my work. | 6.4 (0.9) | 5.6 (1.6) | <0.001 |
| The culture in my unit/clinical area makes it easy to speak up about patient safety concerns. | 6.2 (0.9) | 5.4 (1.6) | <0.001 |
| My colleagues (doctors and/or nurses) react appropriately, when I speak up about my concerns about patient safety. | 5.9 (0.9) | 5.4 (1.2) | <0.001 |
| My shift supervisors (person in charge of a shift) react appropriately, when I speak up about my patient safety concerns. | 5.9 (1.0) | 5.5 (1.4) | 0.009 |
| <i>Encouraging Environment for Speaking up, mean scale score</i> | 5.9 (0.9) | 4.9 (1.4) | <0.001 |
| In my unit/ clinical area, I observe others speaking up about their patient safety concerns. | 5.6 (1.2) | 5.2 (1.5) | 0.028 |
| I am encouraged by my colleagues (doctors and/or nurses) to speak up about patient safety concerns. | 6.0 (1.1) | 4.6 (1.7) | <0.001 |
| I am encouraged by my shift supervisor (person in charge during a shift) to speak up about patient safety concerns. | 6.1 (1.1) | 4.9 (1.8) | <0.001 |
| <i>Resignation towards Speaking up, mean scale score</i> | 2.5 (1.1) | 3.2 (1.4) | <0.001 |
| When I have patient safety concerns it is difficult to bring them up. | 2.0 (1.1) | 2.4 (1.6) | 0.002 |
| Having to remind staff of the same safety rules again and again is frustrating. | 3.1 (1.7) | 3.9 (2.1) | <0.001 |
| Sometimes I become discouraged because nothing changes after expressing my patient safety concerns. | 2.5 (1.5) | 3.1 (1.9) | 0.004 |
| <i>Total speak up climate score (mean across items)</i> | 5.9 (0.7) | 5.2 (1.0) | <0.001 |

¹ negatively worded items are reverse coded for the total score.
² p-values: Welch's t-test for unequal variances

400 Table 2: comparison of mean (SD) responses to climate survey items for our department and the Swiss
401 comparison.

402