1 2 3	The impact of a 22-month multi-step implementation programme on speaking-up behaviour in an academic anaesthesia department
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21	Running title: the effect of a 22-Month speaking-up programme

## 22 Abstract

#### 23 Background

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

#### 29 Methods

Before implementing a 22-month multistep programme for establishing and strengthening
speaking-up at our institution, we assessed perceived safety culture using the "Safety Attitudes Questionnaire". After programme completion, participants completed parts of the
same "Safety Attitudes Questionnaire" relevant to speaking-up, and pre- and post-results
were compared. Additionally, levels of speaking-up and assertive communication were compared with a Swiss benchmark using results from the "Speaking-up About Patient Safety
Questionnaire".

## 37 Results

"Safety Attitudes Questionnaire" scores were significantly higher after programme completion 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
(4.0, 5.0) versus 4.0 (4.0, 4.0) p=0.002, Median (1st quartile, 3rd quartile)) (n = 34). Our composite score on the "Speaking-Up About Patient Safety Questionnaire" was significantly
higher (5.9 ± 0.7 versus 5.2 ± 1.0, mean ± standard deviation, p < 0.001) than the benchmark</li>
(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 a clear resolution.<sup>1, 2, 3</sup> According to the Joint Commission's sentinel event data from 2015, 55 56 the failure to speak up was one of the top three root causes for adverse events in the peri-57 operative period.<sup>4</sup> 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 workers had chosen to withhold voice within the past four weeks.<sup>5</sup> Several barriers for 59 60 speaking-up have been identified in the perioperative setting, including perceived ineffec-61 tiveness, presence of patients and authority gradients.<sup>1</sup>, <sup>6</sup> 62 Research on the implementation of speaking-up has mainly focused on single groups, including nursing students,<sup>7</sup> medical students,<sup>8</sup> and residents.<sup>9</sup>, <sup>10</sup> In general, implementation of 63 speaking-up has demonstrated varying success,<sup>11</sup>, <sup>12</sup> but common themes include: necessity 64 65 for an implementation programme involving all members of staff, education to support a transformation in organisational culture,<sup>13</sup> and addressing norms and communication behav-66 iours.<sup>14</sup> In short, strengthening a culture of speaking-up is an ongoing challenge<sup>15</sup> but also 67 68 crucial to increasing patient safety.

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

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

## 77 Methods:

## 78 Study institution and population:

The study was performed in the Cantonal Hospital of Baden, a 382 bed teaching hospital of Zurich University, which annually treats more than 20`000 inpatients and more than 170`000 outpatients. All staff members of the department of anaesthesia, i.e. nurse and physician anaesthetists (both residents and consultants) employed at any time during the 22 months were exposed to the implementation programme. The requirement for approval of our

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-

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

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

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

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 validated tool to assess<sup>16</sup>, <sup>17</sup> healthcare workers' perceptions of patient safety related atti-102 103 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 validated<sup>18</sup> and successfully tested in 10 Swiss hospitals<sup>19</sup> and transcribed to the Survey Mon-107 108 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, C easylearn

schweiz ag, comprised of three components. Firstly, background knowledge and the ra-

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118 tionale for speaking-up were presented together with instructions including the two-challenge rule,<sup>20</sup> and providing coaching in advocacy-inquiry with specific examples. The second 119 120 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 we assigned as many staff members as rostering allowed during the pandemic: 128 129 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

anaesthesia induction sequence with scripted speaking-up situations with an acting in structor (75 participants) in October 2020,

interdisciplinary team-training sessions for same-day surgery teams, and obstetric anaes thesia teams, with special focus on speaking-up in debriefings (29 participants from our
 department) in April 2021

Scenarios and teaching elements were developed and tested prior to study-use by the Author C.S., a trained instructor for medical simulation with experience developing standardised scenarios for measurement and research,<sup>21</sup> then refined by the authors C.S., F.W. and M.H. using a modified Delphi approach, and finally tested by fellow simulation instructors.

Additionally, the programme was accompanied by a continuous awareness campaign including various lectures and workshops reiterating the topics of the online course (background knowledge and the rationale for speaking-up, instructions and suggestions for providing speaking-up, and coaching in advocacy-inquiry with specific examples), and an interview with the head of the department in the hospital newspaper, in which he discussed hierarchy 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

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 –

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.<sup>22</sup>

#### 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

the following three questions from the "Safety Attitudes Questionnaire" used for the base-157 158 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. • In this clinical area, it is difficult to discuss errors. 161 162 • 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".<sup>23</sup> 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-
- sided p-values < 0.05 were considered statistically significant. All statistical analyses were
- 179 conducted using R version 4.0.2<sup>24</sup>
- 180 To compare the pre- and post-implementation results of the three relevant questions on the
- 181 Safety Attitudes Questionnaire (1° 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 1<sup>st</sup> and 3<sup>rd</sup> 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.<sup>23</sup>
- 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
- 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).
- Table 1: comparison of median (1<sup>st</sup> Q, 3<sup>rd</sup> Q) responses to Safety Attitude Questionnaire items pre- and
   post-implementation.

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#### 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 this study were higher when compared to the Swiss perioperative care sample.<sup>6</sup> Respon-209 210 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

We found that the 22 month implementation programme was associated with higher levels
 of self-reported speaking-up behaviour, as evidenced by a significant improvement in two of
 three elements on the post-implementation Safety Attitudes Questionnaire items addressing
 10

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

Although or study did not investigate the effects of each separate intervention within the programme, evidence does suggest that leader inclusiveness and leadership support is critical – as such, we feel that our head of department providing interviews, lectures, and a scripted video inviting to speaking-up was essential for the programme's success and patient-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.

Although the higher over-all scores in the Speaking-up About Patient Safety Questionnaire as
compared to the benchmark of similar healthcare institutions in Switzerland suggest a positive effect of our implementation programme, some results are sobering, albeit not unexpected. 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:

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

#### 257 Limitations of our study:

Our study is limited by its small size and relatively small response rate. Due to the requirement that study participants completed the whole implementation programme and staff fluctuation over the 22 months, overall numbers were smaller than expected. Additionally, the prominence of leadership support in "safe behaviour" makes a Hawthorne effect highly 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 Hofstedes 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

A long term, inclusive and multi-step programme for establishing speaking-up was successfully implemented at our institution. Attitude and climate towards safety in our department
improved after implementation according to "SAQ"-scores; the "Speaking-Up About Patient
Safety Questionnaire" respondents at our institution reported higher levels of psychological
safety, a more positive encouraging environment, and described less resignation towards
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
- the change in culture and behaviour towards safer healthcare, increases in levels of speak-
- ing-up can indeed be achieved.

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- 292 Conflicts of interests
- 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 imp	lementation program	me – of 177 member	s of staff present	at some time dur-
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- 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
- 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.

Table 2: comparison of mean (SD) responses to climate survey items for our department andthe Swiss comparison.

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Safety Attitudes Questionnaire (measures on a 6-point scale)

median (1<sup>st</sup> quartile, 3<sup>rd</sup> quartile)

p value

<u>(n=34)</u>	pre-implementation	post-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 <i>,</i> 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 (1<sup>st</sup> Q, 3<sup>rd</sup> Q) responses to Safety Attitude Questionnaire items pre- and

398 post-implementation.

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Items and scales (measure on a 7-point Likert scale)	mean (SD)		p value
	This sample (n=65)	Swiss perioperative care sample (n=360)	
Psychological Safety for Speaking up, mean scale score	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 pa- tient 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
Encouraging Environment for Speaking up, mean scale score	5.9 (0.9)	4.9 (1.4)	<0.001
In my unit/ clinical area, I observe others speaking up about their patient	5.6 (1.2)	5.2 (1.5)	0.028
safety concerns.			
I am encouraged by my colleagues (doctors and/or nurses) to speak up	6.0 (1.1)	4.6 (1.7)	<0.001
about patient safety concerns.			
I am encouraged by my shift supervisor (person in charge during a shift) to	6.1 (1.1)	4.9 (1.8)	<0.001
speak up about patient safety concerns.			
Resignation towards Speaking up, mean scale score	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 frustrat-	3.1 (1.7)	3.9 (2.1)	<0.001
ing.			
Sometimes I become discouraged because nothing changes after express-	2.5 (1.5)	3.1 (1.9)	0.004
ing my patient safety concerns.			
Total speak up climate score (mean across items)	5.9 (0.7)	5.2 (1.0)	<0.001
<sup>1</sup> negatively worded items are reverse coded for the total score.			
<sup>2</sup> 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.