PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	'Saying it without words': a qualitative study of oncology staff's experiences with speaking-up about safety concerns
AUTHORS	Schwappach, David; Gehring, Katrin

VERSION 1 - REVIEW

REVIEWER	Anthony Easty, PhD University Health Network/University of Toronto Toronto, Ontario, Canada
REVIEW RETURNED	04-Mar-2014

GENERAL COMMENTS	This work focuses on an important area of concern in a variety of health care environments; the issue of team interactions and dynamics, and the extent to which team members feel empowered to speak up if they determine that another team member is providing care in a manner which may represent a safety concern. The paper introduces the topic well and uses appropriate references to build its case. There are a few concerns that need to be addressed in the form of revisions prior to publication. Firstly, in the data analysis section, the manner in which codes were assigned to the observed issues is in line with normal practice for this type of research. However, it is usual to report on the initial level of agreement between two researchers operating independently from each other, using a Kappa test for level of agreement. This is important, since it is a measure of the initial level of agreement between the two researchers. I believe that it should be included here. The subsequent iterative revision is reasonable once this initial analysis has been done, especially if the initial level of agreement is, itself, at a fairly high level. If the initial level of agreement is low, this casts doubt on the validity of the coding process, and indicates a high level of subjectivity. The presentation of data is somewhat sparse. Table 1 gives the Characteristics of participants (and here it would be nice to include the Total of 32 rather than leave the reader to work it out). Figure 1 gives examples of safety issues which triggered safety concerns, but no "n's" are given for the frequency of each issue. It would be relatively easy to incorporate this into Figure 1 and this knowledge would give at least an indication of the relative prevalence of each issue. Without this, the reader has to take the textual analysis at face value and has no way of validating the conclusions that are presented in the text. Ideally, it would be good to know which concerns were raised by which professional groups. I don't know whether space permits the inclusion of these data, but it would be helpful to see them.

	The paper is generally clearly written with just a few minor fixes required to the English. Specifically, the repeated use of "Contrary" at the beginning of sentences is not correct and I suggest the use of "In contrast" instead. There are a few other very minor fixes required, and a critical edit will quickly bring those out. Finally, in Acknowledgements, a number of clinicians at study hospitals are named. If these people were study participants, this is a breach of their confidentiality. I see that the study was exempted from full ethical review, but even with an expedited review, one should never identify study participants in this fashion unless it was explicitly stated to them that their names would be published and they consented to this at the time. There are other ways to thank participants for their help with a study while preserving their anonymity.

REVIEWER	Jane Barnsteiner, PhD, RN, FAAN, Professor Emerita University of Pennsylvania School of Nursing Philadelphia, PA USA
REVIEW RETURNED	06-Mar-2014

GENERAL COMMENTS	This is a very important and timely topic. I have a few suggestions to strengthen the manuscript. Re # of hospitals. Please clarify. You state 6 but it appears to be 5 or 7. Were the children's hospitals part of the other hospitals? While this was a qualitative study, I would have liked to know if there were any differences among those from pediatric vs adult facilities and also if there were differing responses from those with less than 18 months of experience and thos with more than 18 months as the groups basically appear equal in number. This would be important to conclusions. It appears there are a number of sub-themes to "speaking up": 1)hierarchy and social norms; 2) lack of communication skills to "speak up: and 3) voicing tactics. It may be helpful to separate them out as they would each have a different intervention. I found it noteworthy the investigators did not offer any suggestions for changes in practice related to their findings. For example, socialization of medical and nursing students to the importance of ignoring the hierarchy when patient safety is at risk and professional communication approaches to use for various situations.

REVIEWER	Audrey Lyndon Associate Professor University of California, San Francisco United States
REVIEW RETURNED	10-Mar-2014

GENERAL COMMENTS	Thank you for the opportunity to review this original research study of the experiences of oncology staff in Switzerland with communicating safety concerns. Study strengths include exploration of an important question and sampling from multiple facilities to increase transferability of findings. Overall the methods are appropriate to the research question and the study makes a contribution to the literature on speaking up about safety concerns. Several opportunities for further strengthening the manuscript are noted, as follows:

	1) The abstract overstates the findings, as do a few other sections of the manuscript. The study design does not support the abstract statement "We found a strong association of clinical safety issues with speaking up behavior," as no associations were tested nor could they be tested in this qualitative study. Similarly, in the discussion it is a bit beyond the results to say that other issues are significantly more difficult to voice…rather the participants in this study found other issues more difficult to voice. Likewise, the idea that clinicians devote considerable resources to evaluating the situation was not really developed in the manuscript. The authors did show that clinicians think about how to present speaking up and may modify their strategies depending on the recipient's status. If the data support that the efforts expended in considering strategy and avoiding intrusiveness are indeed extensive, then these aspects should be developed in greater depth – perhaps including any information that might be available about how these efforts were balanced with the clinicians' other responsibilities. 2) The noted strength about gestures and mimics in the "Strengths and Limitations" summary is not mentioned at all in the abstract, so this is a bit confusing. 3) Page 3, lines 15-19 report a fairly old case (2001 publication). It would be helpful note this as an early or classic example, and/or more recent examples could be given which would increase the power of the example. 4) The literature around speaking up behaviors in medicine is a bit broader than what is covered here. Some additional examples include Blatt, Christianson, Sutcliffe, & Rosenthal, 2006; Lyndon, 2008; Rance et al., 2013; Sutcliffe, Lewton, & Rosenthal, 2004. In particular it would be interesting and useful to draw some comparisons between this study's findings and what literature is available on speaking up by patients (e.g. Rance as well as the manuscript author's other studies). 5) It would be helpful to include the interview guide so that we may understand more clearly how the questions were framed during the interviews. 6) There is no discussion of reflexivity, which is considered an important standard of qualitative rigor (cf. Tracy, 2010; Whittemore, Chase, & Mandle, 2001) 7) Discussion, page 9, line 52 – The statement "… suggest nurses and doctors in oncology frequently experience…." Seems a bit misleading, as there does not appear to be any way to assess frequency of events from the data collected, not any comparison with the frequency of non-events. Articles cited: Blatt, R., Christianson, M. K., Sutcliffe, K. M., & Rosenthal, M. M. (2006). A sensemaking lens on reliability. Journal of Organizational Behavior, 27, 897-917. doi: DOI: 10.1002/job.392 Lyndon, A. (2008). Social and environmental conditions creating fluctuating agency for safety in two urban academic birth centers. Journal of Obstetric, Gynecologic, and Neonatal Nursing, 37(1), 13-23. doi: 10.1111/j.1552-6909.2007.00204.x Rance, S., McCourt, C., Rayment, J., Mackintosh, N., Carter, W.,

Watson, K., & Sandall, J. (2013). Women's safety alerts in maternity care: is speaking up enough?. BMJ Qual Saf, 22(4), 348-355. doi: 10.1136/bmjqs-2012-001295
Sutcliffe, K. M., Lewton, E., & Rosenthal, M. M. (2004). Communication failures: An insidious contributor to medical mishaps. Academic Medicine, 79, 186-194.
Tracy, S. J. (2010). Qualitative Quality: Eight "Big-Tent" Criteria for Excellent Qualitative Research. Qualitative Inquiry, 16(10), 837-851. doi: 10.1177/1077800410383121
Whittemore, R., Chase, S. K., & Mandle, C. L. (2001). Validity in qualitative research. Qualitative Health Research, 11(4), 522-537. doi: 10.1177/104973201129119299

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name Anthony Easty, PhD
Institution and Country University Health Network/University of Toronto
Toronto, Ontario, Canada
Please state any competing interests or state 'None declared': None declared.

This work focuses on an important area of concern in a variety of health care environments; the issue of team interactions and dynamics, and the extent to which team members feel empowered to speak up if they determine that another team member is providing care in a manner which may represent a safety concern. The paper introduces the topic well and uses appropriate references to build its case.
Thank you.

There are a few concerns that need to be addressed in the form of revisions prior to publication. Firstly, in the data analysis section, the manner in which codes were assigned to the observed issues is in line with normal practice for this type of research. However, it is usual to report on the initial level of agreement between two researchers operating independently from each other, using a Kappa test for level of agreement. This is important, since it is a measure of the initial level of agreement between the two researchers. I believe that it should be included here. The subsequent iterative revision is reasonable once this initial analysis has been done, especially if the initial level of agreement is, itself, at a fairly high level. If the initial level of agreement is low, this casts doubt on the validity of the coding process, and indicates a high level of subjectivity.
Thank you for this comment. In the revision (methods/data analysis) we now report interrater reliability (kappa).

The presentation of data is somewhat sparse. Table 1 gives the Characteristics of participants (and here it would be nice to include the Total of 32 rather than leave the reader to work it out).
Yes, sorry, the total number is now included in the table header.

Figure 1 gives examples of safety issues which triggered safety concerns, but no "n's" are given for the frequency of each issue. It would be relatively easy to incorporate this into Figure 1 and this knowledge would give at least an indication of the relative prevalence of each issue. Without this, the reader has to take the textual analysis at face value and has no way of validating the conclusions that are presented in the text. Ideally, it would be good to know which concerns were raised by which professional groups. I don't know whether space permits the inclusion of these data, but it would be helpful to see them.
Thank you for this helpful comment. In the original figure 1 we reported specific <u>examples</u> of concerns so attaching a frequency to each issue would not be very useful from our perspective (many examples would get n=1). In the text, we provide the distribution of categories of concerns which is what we feel is the information asked for by the referee. We changed figure 1 so that it includes the number of reports in each category, and also added the number of reports by professional group. We also added the categories "patient communication" and "other" to make this display complete.

The paper is generally clearly written with just a few minor fixes required to the English. Specifically, the repeated use of "Contrary" at the beginning of sentences is not correct and I suggest the use of "In contrast" instead. There are a few other very minor fixes required, and a critical edit will quickly bring those out.
Thank you, these errors have been fixed.

Finally, in Acknowledgements, a number of clinicians at study hospitals are named. If these people were study participants, this is a breach of their confidentiality. I see that the study was exempted from full ethical review, but even with an expedited review, one should never identify study participants in this fashion unless it was explicitly stated to them that their names would be published and they consented to this at the time. There are other ways to thank participants for their help with a study while preserving their anonymity.
Thank you for this cautionary note. Of course, the individuals listed in the Acknowledgements are NOT the interview participants. They are clinicians that mentored the study in the hospitals. We changed the wording a little to make this clearer.

Reviewer: 2
Reviewer NameJane Barnsteiner, PhD, RN, FAAN, Professor Emerita
Institution and Country University of Pennsylvania School of Nursing
Philadelphia, PA USA
Please state any competing interests or state 'None declared': No competing interests

This is a very important and timely topic. I have a few suggestions to strengthen the manuscript.
Re # of hospitals. Please clarify. You state 6 but it appears to be 5 or 7. Were the children's hospitals part of the other hospitals?
Thank you. We hope we could now clarify this issue. The additional statement reads "One university hospital participated with the adult and the paediatric oncology department."
While this was a qualitative study, I would have liked to know if there were any differences among those from pediatric vs adult facilities and also if there were differing responses from those with less than 18 months of experience and thos with more than 18 months as the groups basically appear equal in number. This would be important to conclusions.
Thank you for this comment. We added the distribution of reports by professional group and for the pediatric departments in figure 1, which you may find useful. In the chapter "types of voice used" we added information about specific reports obtained from pediatric hospitals. It reads: "Clinicians working at the paediatric oncology units were very much concerned with the presence of parents in situations requiring speaking up and reported to switch to non-verbal communication (e.g., harrumphing) with the expectation that parents would not understand the information." From the interviews we had no indication that months of work experience in oncology was per sé related to speaking up behaviors. However, months of experience is strongly related to age, function and hierarchical status and we found it hard to detangle these in a qualitative study. Were appropriate, we point to differences in behavior between those of higher and lower hierarchical status (e.g., seniors vs. residents). We found that types of voice used seemed to be affected by age and/or hierarchical status. We feel that a more intense treatment of the differences in speaking up according to staff or hospital characteristics would be better examined in quantitative research.

It appears there are a number of sub-themes to "speaking up": 1)hierarchy and social norms; 2) lack of communication skills to "speak up: and 3) voicing tactics. It may be helpful to separate them out as they would each have a different intervention.
Yes, there are a number of sub-themes and different ways of organizing them are possible. We discussed your suggestion but decided to retain the current structure of the discussion. However, we elaborate on the "intervention" idea in response to the following comment.
I found it noteworthy the investigators did not offer any suggestions for changes in practice related to their findings. For example, socialization of medical and nursing students to the importance of ignoring the hierarchy when patient safety is at risk and professional communication approaches to use for various situations.

Yes, you are absolutely right, thank you. We added a para on training programs in the "implications for practice and future research" section in the discussion.

Reviewer: 3
Reviewer Name Audrey Lyndon
Institution and Country Associate Professor
University of California, San Francisco United States
Please state any competing interests or state 'None declared': None declared

Thank you for the opportunity to review this original research study of the experiences of oncology staff in Switzerland with communicating safety concerns. Study strengths include exploration of an important question and sampling from multiple facilities to increase transferability of findings. Overall the methods are appropriate to the research question and the study makes a contribution to the literature on speaking up about safety concerns. Several opportunities for further strengthening the manuscript are noted, as follows:
Thank you for your compliment.

1) The abstract overstates the findings, as do a few other sections of the manuscript. The study design does not support the abstract statement "We found a strong association of clinical safety issues with speaking up behavior," as no associations were tested nor could they be tested in this qualitative study. Similarly, in the discussion it is a bit beyond the results to say that other issues are significantly more difficult to voice…rather the participants in this study found other issues more difficult to voice. Likewise, the idea that clinicians devote considerable resources to evaluating the situation was not really developed in the manuscript. The authors did show that clinicians think about how to present speaking up and may modify their strategies depending on the recipient's status. If the data support that the efforts expended in considering strategy and avoiding intrusiveness are indeed extensive, then these aspects should be developed in greater depth – perhaps including any information that might be available about how these efforts were balanced with the clinicians' other responsibilities.
Thank you for your thorough reading! In the revision, we relaxed the conclusions and try being more precise and less "quantitative"-toned. Thank you.

2) The noted strength about gestures and mimics in the "Strengths and Limitations" summary is not mentioned at all in the abstract, so this is a bit confusing.
Thank you! We added this to the abstract.

3) Page 3, lines 15-19 report a fairly old case (2001 publication). It would be helpful note this as an early or classic example, and/or more recent examples could be given which would increase the power of the example.
Done

4) The literature around speaking up behaviors in medicine is a bit broader than what is covered here. Some additional examples include Blatt, Christianson, Sutcliffe, & Rosenthal, 2006; Lyndon, 2008; Rance et al., 2013; Sutcliffe, Lewton, & Rosenthal, 2004. In particular it would be interesting and useful to draw some comparisons between this study's findings and what literature is available on speaking up by patients (e.g. Rance as well as the manuscript author's other studies).
Thank you for these helpful suggestions. We expanded the introduction and now present some more research about speaking up, including your suggestions.
Though we also do agree that it would interesting to make the connection to patients' speaking up behaviors we decided to leave this to future work. We believe that a valuable comparison would need more space and systematic analysis.

5) It would be helpful to include the interview guide so that we may understand more clearly how the questions were framed during the interviews.
Yes, we agree. Unfortunately, the interview guide is only available in German language and we believe it would only be helpful if we ensured a high-quality translation, including the introduction of the interview, and all prompts, etc. Otherwise it would be rather misleading. We therefore decided to present the main questions in the body of the text and not as original in the appendix and hope that this meets your approval.

6) There is no discussion of reflexivity, which is considered an important standard of qualitative rigor (cf. Tracy, 2010; Whittemore, Chase, & Mandle, 2001)
Yes, thank you. We now added a para on reflexivity in the limitations section.

7) Discussion, page 9, line 52 – The statement "… suggest nurses and doctors in oncology frequently experience…." Seems a bit misleading, as there does not appear to be any way to assess frequency of events from the data collected, not any comparison with the frequency of non-events.
Yes, we agree that the term frequently suggests a quantification which is not possible from the data. However, what we can say is that these are not rare, single events but occur "unexceptionally". We now chose the term "commonly".

Articles cited:
Blatt, R., Christianson, M. K., Sutcliffe, K. M., & Rosenthal, M. M. (2006). A sensemaking lens on reliability. Journal of Organizational Behavior, 27, 897-917. doi: DOI: 10.1002/job.392
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Whittemore, R., Chase, S. K., & Mandle, C. L. (2001). Validity in qualitative research. Qualitative Health Research, 11(4), 522-537. doi: 10.1177/104973201129119299
Thank you so much for providing the detailed reference list. This was extremely helpful.

VERSION 2 – REVIEW

REVIEWER	Anthony Easty, PhD University Health Network/University of Toronto, Toronto, Ontario, Canada
REVIEW RETURNED	21-Apr-2014

GENERAL COMMENTS	This paper presents an interesting and important investigation into the culture of speaking up about safety concerns in seven oncology treatment centres, both adult and paediatric. A structured interview process is used to elicit feedback from a range of health care professionals in these units, and although the numbers involved are relatively small, the findings draw out and confirm important barriers to effective communication, and also highlight hierarchical barriers as well. The dangers associated with impaired communications are clearly identified, and some of the impacts are potentially severe. This work serves to illustrate the importance of trying to change health care cultures to make it acceptable and non threatening for any member of a team to speak out about a practice that they observe and have reason to believe is wrong, or even dangerous. It is well-established that safe work environments include a culture of openness, where even the most junior member of a team feels free to express his or her concerns about a potential safety threat. It is imperative that we

	all work toward the universal adoption of such an approach in health care. This paper recommends that teaching and training health professions in assertive communication be undertaken. In addition to this, if we wish these behaviours to "stick", we need to focus not just on students in the health care professions, who are often the most junior members of the care teams and most vulnerable to censure, but on senior team members, who must lead by example, and work to create an environment where more junior, less powerful, colleagues feel empowered to speak out when they observe a potentially hazardous situation or practice. This is a very nice paper with important messages for the medical community, and the authors have done a nice job of revisions. Just a few minor editorial points that I feel should be addressed prior to publication (key words shown in caps below for ease of identification: Page 2, Abstract Results, .."how" to say it. The quotation mark style is incorrect for the first quote. This is also the case in the first paragraph of page 8. Page 4, first paragraph, ..dependent ON situational factors.. Same paragraph,..preserve good relations WITH their co-workers.. Page 4, last sentence, could not access THEIR own experiences ad-hoc. Page 5, suggested re-wording, One university hospital participated with both its adult and paediatric oncology departments. Page 5, Inter-rater (insert a hyphen). Page 6, Participants' speaking up behaviour was strongly related to THE clinical safety issue. Page 9, this may be a translation issue, and I don't want to twist the meaning, but the phrase, "Just a little pretending the dumb" might be better stated as "Pretending to be a little dumb", provided that was the real meaning of the person interviewed. Page 12, including PAEDIATRIC departments (since the spelling used on page 5 is the UK "paediatric", it seems best to stick to that. Page 13, first paragraph, Should be FOURTH, not FORTH.

REVIEWER	Jane Barnsteiner, PhD, RN, FAAN University of Pennsylvania School of Nursing Philadelphia, PA, USA
REVIEW RETURNED	22-Apr-2014

- The reviewer completed the checklist but made no further comments.

REVIEWER	Audrey Lyndon University of California, San Francisco United States

REVIEW RETURNED	21-Apr-2014

GENERAL COMMENTS	This revision successfully addresses almost all reviewer requests. I still find the use of 'strongly related' to be a bit of a reach. I hesitate to place the authors in the middle of a dispute about qualitative rigor so can accept the addition of kappa although it is not a necessary indicator of quality. At the same time the statement on page 12 about accuracy being threatened by subjectivity is unlikely to be understood by the average reader without considerable elaboration. While standards for qualitative rigor remain somewhat contested, there is not an expectation of exact replicability due to increasing understanding of the influence of the investigator on all forms of research, and the idea that the analysis could somehow be validated as "accurate" in the sense of the only "correct" analysis is inconsistent with most current understandings of qualitative rigor. As the authors indicate in the subsequent discussion it is not so much "subjectivity" that threatens the quality of a qualitative analysis, but allowing unchecked and unexamined researcher concerns to overshadow the elicited concerns of participants. The procedures described are quite appropriate but I fear the leading sentence contributes to readers' potential misunderstanding of standards for qualitative rigor.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name Anthony Easty, PhD
Institution and Country University Health Network/University of Toronto
Toronto, Ontario, Canada
Please state any competing interests or state 'None declared': None declared.

This paper presents an interesting and important investigation into the culture of speaking up about safety concerns in seven oncology treatment centres, both adult and paediatric. A structured interview process is used to elicit feedback from a range of health care professionals in these units, and although the numbers involved are relatively small, the findings draw out and confirm important barriers to effective communication, and also highlight hierarchical barriers as well.

The dangers associated with impaired communications are clearly identified, and some of the impacts are potentially severe. This work serves to illustrate the importance of trying to change health care cultures to make it acceptable and non threatening for any member of a team to speak out about a practice that they observe and have reason to believe is wrong, or even dangerous. It is well-established that safe work environments include a culture of openness, where even the most junior member of a team feels free to express his or her concerns about a potential safety threat. It is imperative that we all work toward the universal adoption of such an approach in health care.

This paper recommends that teaching and training health professions in assertive communication be undertaken. In addition to this, if we wish these behaviours to "stick", we need to focus not just on students in the health care professions, who are often the most junior members of the care teams and most vulnerable to censure, but on senior team members, who must lead by example, and work to create an environment where more junior, less powerful, colleagues feel empowered to speak out when they observe a potentially hazardous situation or practice.

This is a very nice paper with important messages for the medical community, and the authors have done a nice job of revisions. Just a few minor editorial points that I feel should be addressed prior to publication (key words shown in caps below for ease of identification:

Thank you very much for your encouraging comments! We made all corrections as suggested below.

Page 2, Abstract Results, .."how" to say it. The quotation mark style is incorrect for the first quote. This is also the case in the first paragraph of page 8.
Page 4, first paragraph, ..dependent ON situational factors.. Same paragraph,..preserve good relations WITH their co-workers..
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Page 12, including PAEDIATRIC departments (since the spelling used on page 5 is the UK "paediatric", it seems best to stick to that.
Page 13, first paragraph, Should be FOURTH, not FORTH.

Reviewer: 2
Reviewer Name Jane Barnsteiner, PhD, RN, FAAN, Professor Emerita
Institution and Country University of Pennsylvania School of Nursing
Philadelphia, PA USA
Please state any competing interests or state 'None declared': No competing interests

Authors did a nice job of addressing the suggested revisions.
Thank you!
Reviewer: 3
Reviewer Name Audrey Lyndon
Institution and Country Associate Professor
University of California, San Francisco United States
Please state any competing interests or state 'None declared': None declared

This revision successfully addresses almost all reviewer requests.
I still find the use of 'strongly related' to be a bit of a reach.
We understand your concern but have decided to keep this wording because it reflects best what we found in the data.

I hesitate to place the authors in the middle of a dispute about qualitative rigor so can accept the addition of kappa although it is not a necessary indicator of quality.
Thank you.

At the same time the statement on page 12 about accuracy being threatened by subjectivity is unlikely to be understood by the average reader without considerable elaboration. While standards for qualitative rigor remain somewhat contested, there is not an expectation of exact replicability due to increasing understanding of the influence of the investigator on all forms of research, and the idea that the analysis could somehow be validated as "accurate" in the sense of the only "correct" analysis is inconsistent with most current understandings of qualitative rigor. As the authors indicate in the subsequent discussion it is not so much "subjectivity" that threatens the quality of a qualitative analysis, but allowing unchecked and unexamined researcher concerns to overshadow the elicited concerns of participants. The procedures described are quite appropriate but I fear the leading sentence contributes to readers' potential misunderstanding of standards for qualitative rigor.
Thank you for these thoughts! We agree and rephrased the sentence to "*Second, as qualitative research the accuracy of our study is threatened by undetected researcher influences.****" We hope this meets your approval.**