PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Predictors of healthcare professionals' attitudes towards family involvement in safety-relevant behaviours: A cross-sectional factorial survey study
AUTHORS	Davis, Rachel; Savvopoulou, Maria; Shergill, Raman; Shergill, Saman; Schwappach, David

VERSION 1 - REVIEW

REVIEWER	Kaarin Michaelsen, PhD/MD University of Pittsburgh, Department of Anesthesia Pittsburgh, Pennsylvania United States
REVIEW RETURNED	04-Jun-2014

GENERAL COMMENTS	Overall, a very interesting paper on a grossly understudied -- yet quite important-- subject with a well-designed method (vignettes) for measuring outcomes. Comments: 1) Abstract: It would be helpful to clarify in the initial participation/setting section precisely what type of hospitals were involved (i.e. specialty vs. general), as that could markedly affect the way HCPs would respond to the vignettes (see notes below); a notation of whether the HCPs were serving on general medicine wards, surgical wards, or intensive care units would also be helpful (see rationale below). In the results section of the abstract, the authors should provide the actual percentage of HCPs who supported family members' intervention, as that statistic is difficult to locate otherwise and would lend more support to the data in this section. 2) Results: In the section entitled, "Correlations between affective rating scores and key outcome measures," the first line simply notes that there are associations between HCP's mean affective ratings scores and responses to the 4 attitudinal judgments. However, given that the p-values for two of the four] are not significant, it would be better to state that fact up front and then note the association. It would also make the contrast between the other key outcome measures more obvious. In the Discussion section, the authors note that "these results could potentially suggest that HCPs actually view family involvement differently, as it involves a different dynamic to the patient interacting with them." My own anecdotal evidence would tend to support that conclusion, and I would encourage the authors to continue to pursue this line of inquiry to ascertain how this dynamic operates in other contexts and iterations. Specifically, I would suggest that they consider expanding their work (possibly for inclusion in this paper) to examine how HCPs and family members interact in different settings -- i.e. in the intensive care unit (where family members are often viewed by HCPs as "ancillary team members" with regard to hand

	hygiene and other patient safety measures because of the highly immunocompromised nature of the patients) vs. on a general medical floor. While many of the variables the authors identify as predictors for HCPs' response may still apply, it may indeed be the case that context proves to be more important as an overall predictive factor. Both doctors and nurses on intensive care unit floors frequently experience situations in which family members question or challenge them, which might result in higher affective ratings in that context than was seen among nurses in this study as currently reported. If the authors have the data to include in this paper information comparing intensive care units vs. general medicine floors, it would greatly strengthen some of the paper's broader conclusions and key outcome measures, and it would also help to show to what extent a specific care setting affects these results (a very interesting point and one that we also know little about.) Minor points: There are several small grammatical errors scattered throughout the paper (e.g. "was hands" in abstract, some missing commas, and some seemingly extraneous parentheticals).

REVIEWER	Dr. Christopher Vincent UCL Interaction Centre England
REVIEW RETURNED	24-Jun-2014

GENERAL COMMENTS	The paper investigates factors predicting the attitudes of healthcare professionals, to questioning by the relatives of patients. The questions relate to issues regarding safety. The study used fictitious vignettes to determine if healthcare professionals supported relatives (carers) intervening in care (e.g. approval of their behaviour), the impact on the relationships between carers and HCPs, affective ratings, and how manipulation of the vignette impacted on the above. The paper was well written, concise and interesting, although I think that there is an opportunity to expand on the meaning of the results and speculate on the implications for practice. General comments Introduction and method - How does the study link to organisational reporting and learning systems (e.g. UK NRLS). For example, perhaps the type of incident contained in the scenario (box 1) would be considered a near miss? Although the vignettes were presumably fictitious, is there an onus on those involved to record and report such incidents? This isn't considered in the vignette but could it impact on HCP attitude more than some of the factors that were manipulated? Methods - Was interpretation of the vignettes consistent? For example, if staff at a particular institution had been involved in an initiative to encourage engagement with patients & carers, could this have impacted on their responses? Discussion – How does the chosen method compare to other approaches, for example observing these interactions in situ or observing training or simulation exercises? The claim that you could not systematically manipulate factors is reasonable, but there could be more discussion concerning the trade-off between a controlled

	study and one that seeks to understand the reality of practice. Overall - Mention of “loved ones” – phrasing is entirely reasonable, however is it unnecessarily selective? For example, although not the focus of the study, could such an intervention come from those who weren’t family or weren’t HCPs but didn’t want something to go wrong? Overall – Parts of the study regard attitudes towards human error (e.g. Reason 1991), however there is no reference to this literature. Overall – I would suggest an additional use for the scenarios in gathering qualitative feedback about the situation of interest in order to better understand the perspective of the HCP or patient. I would also be interested in the extreme responses – e.g. if someone did not approve of the intervention in an error condition, why? Specific comments Methods - Terms used to describe participants were very general – for example “data were collected from doctors and nurses” – could there be more information about area of practice, career level, specialism etc, without breaking any condition of anonymity? Methods – Were the participants given a chance to comment on the likelihood of the scenario occurring in reality? Methods – Who wrote the vignettes and how? Why hand washing and wrong meds? Methods & Results - It took time to fully understand the methods and the tables were hard to navigate (e.g. compare line 9 in table 3 with line 12 and 13). Would it be possible to break some of the tables up, improve the formatting or omit parts? Results - Would it be possible to double check the mapping between tables 3&4 and the results section: “results of the regression analysis?” I was unsure if the main text represents all of the notable results in this table (e.g. differences between the hand washing and medication error content). Discussion - In suggesting future research, why not suggest a study investigating the patient perspective on this topic? Box 1: Levels with coding column – hard to follow – don’t think that the alignment is correct. Typo – Abstract – was their hands Typo - Page 13 – patientss Typo – reference 16 – bracket Box 1 legend: Subscript?

REVIEWER	Dr Jane K O'Hara Bradford Institute for Health Research / University of Leeds, UK
REVIEW RETURNED	24-Jun-2014

GENERAL COMMENTS	4) There is some lack of detail in the method. - I would be keen to understand more about how the HCPs were selected. Was it purposive sampling, or randomly selected? If so, how was this done? - I am confused about the development of the survey. There is no detail on development in the submission, and I would expect this, or a reference to where this is published previously. - Linked to this, I would expect a new survey to have been factor analysed, especially given that an affective rating score is used, with the composite of these ratings making up part of the analyses. Cronbach's alpha scores would indicate that scores on the affective ratings are related, but factor analysis would describe better how the ratings hang together conceptually. I believe this paper would benefit from more information on the development of the survey, given that it is so central to the conclusions of the study. 5) There is no mention in the text about ethical approval. Whilst NHS REC approval is not required for studies involving staff, it is good practice to seek approval from another source, e.g. an affiliated university ethics board. 7) I have not used the chow test within STATA, and as such would recommend review by a statistician with this knowledge. - My concern with respect to the statistics is simply the use of a composite score for affective ratings, when this is not a previously validated survey, or has not been established within factor analysis. 10) The results are in general presented well, but in my opinion they would benefit from further sub-headings or some other signposting to aid the reader. - Additionally, in general across the results I think the authors need to make the point that as this is a cross-sectional survey, the results are associations between variables rather than 'effect' of one variable on another, which intimates causality or temporal association. OTHER COMMENTS: I feel that the discussion would benefit from a wider look at the literature on family involvement in care. Paediatrics in particular has a long history of involving families and carers, and there may be work there around the issue of involving patients' families in care. An example of this would be: Eichner et al (2012) 'Patient- and family-centered care and the paediatrician's role' Pediatrics, 129(2):394-404. In general I feel this is a well written paper, that would just benefit from some additional detail in terms of the method, the survey tool used (given its focal role in the results and conclusions), and perhaps a wider discussion on some of the policy imperatives and other literature on the involvement of families in patient-centred care.

VERSION 1 – AUTHOR RESPONSE

Reviewer Name Kaarin Michaelsen, PhD/MD
Institution and Country University of Pittsburgh, Department of Anesthesia, Pittsburgh, Pennsylvania, United States
Please state any competing interests or state ‘None declared’: None Declared

Overall, a very interesting paper on a grossly understudied -- yet quite important-- subject with a well-designed method (vignettes) for measuring outcomes.
Comments: 1) Abstract: It would be helpful to clarify in the initial participation/setting section precisely what type of hospitals were involved (i.e. specialty vs. general), as that could markedly affect the way

HCPs would respond to the vignettes (see notes below); a notation of whether the HCPs were serving on general medicine wards, surgical wards, or intensive care units would also be helpful (see rationale below).

- We now include this information in the abstract (setting)

In the results section of the abstract, the authors should provide the actual percentage of HCPs who supported family members' intervention, as that statistic is difficult to locate otherwise and would lend more support to the data in this section.

- We added this information. The sentence now reads “HCPs supported family member’s intervening (88%) but only 41% agreed that this would have positive effects on the family member/HCP relationship.”

2) Results: In the section entitled, "Correlations between affective rating scores and key outcome measures," the first line simply notes that there are associations between HCP's mean affective ratings scores and responses to the 4 attitudinal judgments. However, given that the p-values for two of the four are not significant, it would be better to state that fact up front and then note the association. It would also make the contrast between the other key outcome measures more obvious.

- Yes, we agree. This has been revised to “HCPs' mean affective rating scores (composite measure) and responses to the 4 attitudinal judgments were only weakly correlated:”

In the Discussion section, the authors note that "these results could potentially suggest that HCPs actually view family involvement differently, as it involves a different dynamic to the patient interacting with them." My own anecdotal evidence would tend to support that conclusion, and I would encourage the authors to continue to pursue this line of inquiry to ascertain how this dynamic operates in other contexts and iterations. Specifically, I would suggest that they consider expanding their work (possibly for inclusion in this paper) to examine how HCPs and family members interact in different settings -- i.e. in the intensive care unit (where family members are often viewed by HCPs as "ancillary team members" with regard to hand hygiene and other patient safety measures because of the highly immunocompromised nature of the patients) vs. on a general medical floor. While many of the variables the authors identify as predictors for HCPs' response may still apply, it may indeed be the case that context proves to be more important as an overall predictive factor. Both doctors and nurses on intensive care unit floors frequently experience situations in which family members question or challenge them, which might result in higher affective ratings in that context than was seen among nurses in this study as currently reported.

- We think this is an interesting and valuable comment. We now include this as suggestion for future research. “We also suggest studying the safety-related interactions between HCP and family members in other medical settings, or even in comparison between settings, to gain a deeper understanding of the relevance of context. For example, we expect that family members of intensive care patients and the roles attributed to them are probably being perceived very differently to other care settings. HCP in intensive care are also more used to being questioned and challenged by family members and may therefore experience less emotional distress when confronted with safety-related interventions by family members.”

If the authors have the data to include in this paper information comparing intensive care units vs. general medicine floors, it would greatly strengthen some of the paper's broader conclusions and key outcome measures, and it would also help to show to what extent a specific care setting affects these results (a very interesting point and one that we also know little about.)

- Again, a very valuable comment. However, we do not have enough data to draw these comparisons. But we mention this idea in the discussion (see response above).

Minor points: There are several small grammatical errors scattered throughout the paper (e.g. "was hands" in abstract, some missing commas, and some seemingly extraneous parentheticals).

- We are sorry for these errors and hope we have corrected them all.

Reviewer Name Dr. Christopher Vincent
Institution and Country UCL Interaction Centre, England
Please state any competing interests or state 'None declared': None declared

The paper investigates factors predicting the attitudes of healthcare professionals, to questioning by the relatives of patients. The questions relate to issues regarding safety. The study used fictitious vignettes to determine if healthcare professionals supported relatives (carers) intervening in care (e.g. approval of their behaviour), the impact on the relationships between carers and HCPs, affective ratings, and how manipulation of the vignette impacted on the above. The paper was well written, concise and interesting, although I think that there is an opportunity to expand on the meaning of the results and speculate on the implications for practice.

General comments
Introduction and method - How does the study link to organisational reporting and learning systems (e.g. UK NRLS). For example, perhaps the type of incident contained in the scenario (box 1) would be considered a near miss? Although the vignettes were presumably fictitious, is there an onus on those involved to record and report such incidents? This isn't considered in the vignette but could it impact on HCP attitude more than some of the factors that were manipulated?

- We appreciate these suggestions. We also agree that there are other, uncaptured factors affecting HCPs responses to the vignettes. In part, these become obvious in the significant differences between the scenarios (hand hygiene and medication error). However, we can only speculate on these and feel that this is beyond the scope of the present work. We also don't know HCPs attitudes towards reporting incidents to the NRLS so to draw associations between our work and this without data would be very hypothetical. So we decided not to include this point in the discussion.

Methods - Was interpretation of the vignettes consistent? For example, if staff at a particular institution had been involved in an initiative to encourage engagement with patients & carers, could this have impacted on their responses?

- Yes, we agree. It is likely that several conditions outside this study affected HCPs' responses. If there were any current activities at hospitals to involve patient and families in safety, this could potentially affected the results. But we have no information about any such activities and whether and how they could have influenced results. We added this as limitation, which reads "We also do not know whether any patient involvement activities in the hospitals may have affected the results."

Discussion – How does the chosen method compare to other approaches, for example observing these interactions in situ or observing training or simulation exercises? The claim that you could not systematically manipulate factors is reasonable, but there could be more discussion concerning the trade-off between a controlled study and one that seeks to understand the reality of practice.

- Yes, indeed. We added this to the discussion. It reads "Still, direct observation of family-HCP interactions relating to patient safety are warranted. This would deepen our understanding of how, where, and by whom such interactions are initiated and how satisfactory they are for HCP and family

members. ”

Overall - Mention of “loved ones” – phrasing is entirely reasonable, however is it unnecessarily selective? For example, although not the focus of the study, could such an intervention come from those who weren’t family or weren’t HCPs but didn’t want something to go wrong?

- Thank you, yes, of course, it could. The idea of voluntary patient safety liaisons runs into this direction. But for the purpose of this study, we need to operationalize the “who” of intervention. It does also make sense in that engagement of family members in patient safety is typically recommended in practice projects, e.g., advisories or information leaflets. It is therefore useful to evaluate HCPs attitudes towards family members’ engagement.

Overall – Parts of the study regard attitudes towards human error (e.g. Reason 1991), however there is no reference to this literature.

- Thank you. We discussed this suggestion. As this is a huge literature and would be a new focus, we think to try and cover it briefly could actually detract from the main focus of the paper.

Overall – I would suggest an additional use for the scenarios in gathering qualitative feedback about the situation of interest in order to better understand the perspective of the HCP or patient. I would also be interested in the extreme responses – e.g. if someone did not approve of the intervention in an error condition, why?

- Thank you, very good suggestion. This would be interesting. We added this as suggestion for future research in the discussion section. It reads “Future research is needed to enlighten the reasons and motivations underlying the attitudes as expressed by HCP in our study. The vignettes could serve as a starting point in qualitative interview studies or focus groups with HCP.”

Specific comments
Methods - Terms used to describe participants were very general – for example “data were collected from doctors and nurses” – could there be more information about area of practice, career level, specialism etc, without breaking any condition of anonymity?

- There is only little additional data on participants available. In the “participants” section, we added that participants we recruited at general medical and surgical wards. In the “results” section, we added the mean years of professional experience of responders.

Methods – Were the participants given a chance to comment on the likelihood of the scenario occurring in reality?

- The survey and vignettes were developed in previous studies and only modified for the family members rather than the patient intervening (but the scenarios remained essentially unchanged). The face validity of the vignettes were examined at the testing stage of the initial survey.

Methods – Who wrote the vignettes and how? Why hand washing and wrong meds?

- The vignettes were written by the authors for the previous studies (referenced in the manuscript). The selection of hand washing and medication error was based on two rationales: First, these two problems are main causes of adverse events and pose serious safety threats to hospitalized patients. Second, the two issues are commonly recommended to patients to watch out for) e.g., in patient advisories).

Methods & Results - It took time to fully understand the methods and the tables were hard to navigate (e.g. compare line 9 in table 3 with line 12 and 13). Would it be possible to break some of the tables up, improve the formatting or omit parts?

- Yes, we are aware that the tables include much data. We tested different alternatives of results display but did not find better options. We believe we should not omit any of the info in the tables. We also don't think we can break the tables up as there would be too many. The tables also follow the same format as previous publications which is nice for consistency.
We now include a column "variable nr" for easier navigation in the tables and also refer to this number in the main text. We hope that this is useful guidance for the reader.

Results - Would it be possible to double check the mapping between tables 3&4 and the results section: "results of the regression analysis?" I was unsure if the main text represents all of the notable results in this table (e.g. differences between the hand washing and medication error content).

- We cross-checked the results in the main text against the tables and verified that all notable results are presented in the text.

Discussion - In suggesting future research, why not suggest a study investigating the patient perspective on this topic?

- Yes, a valuable suggestion. We added the following in the discussion "It would be valuable to examine patients' perspectives on their families intervening. There may be occasions were patients do not want their family members to question staff."

Box 1: Levels with coding column – hard to follow – don't think that the alignment is correct.
Typo – Abstract – was their hands
Typo - Page 13 – patientss
Typo – reference 16 – bracket
Box 1 legend: Subscript?

- Thank you. These errors have been corrected.

Reviewer Name Dr Jane K O'Hara
Institution and Country Bradford Institute for Health Research / University of Leeds, UK
Please state any competing interests or state 'None declared': None declared

Are the methods described sufficiently to allow the study to be repeated?
There is some lack of detail in the method.
I would be keen to understand more about how the HCPs were selected. Was it purposive sampling, or randomly selected? If so, how was this done?

- Purposive sampling was used, we added this information.

I am confused about the development of the survey. There is no detail on development in the submission, and I would expect this, or a reference to where this is published previously.

- We make now clearer that the survey is an adaption of a survey recently developed and published by the authors. It reads "The survey is an adaption of a survey previously developed and applied by the authors23-25."

Linked to this, I would expect a new survey to have been factor analysed, especially given that an

affective rating score is used, with the composite of these ratings making up part of the analyses. Cronbach's alpha scores would indicate that scores on the affective ratings are related, but factor analysis would describe better how the ratings hang together conceptually. I believe this paper would benefit from more information on the development of the survey, given that it is so central to the conclusions of the study.

- As we outlined above, the survey is an adaption of a previously published survey. For the information of this referee, we conducted a principal-component factors analysis with oblique promax rotation of the affective ratings items. The results of this are included in a word document as we could not insert them here (we do not include these in the manuscript). Based on the Eigenvalues, factor loadings and screenplot, we regard the composite score to be justified for the purpose of this analysis. For future analysis, variable q8 (helpfulness) could deserve further inspection.

Are research ethics (e.g. participant consent, ethics approval) addressed appropriately?
There is no mention in the text about ethical approval. Whilst NHS REC approval is not required for studies involving staff, it is good practice to seek approval from another source, e.g. an affiliated university ethics board.

- The study was considered by the Chair of Hampstead's National Research Ethics Committee and classified as exempt from review. No further ethical approval/discussions were necessary.

If statistics are used are they appropriate and described fully?
I have not used the chow test within STATA, and as such would recommend review by a statistician with this knowledge.

- The Chow test is easily implemented in Syntax in STATA. See, e.g., http://www.stata.com/support/faqs/statistics/computing-chow-statistic/

My concern with respect to the statistics is simply the use of a composite score for affective ratings, when this is not a previously validated survey, or has not been established within factor analysis.

- Please see response to similar comment above.

Are the results presented clearly? The results are in general presented well, but in my opinion they would benefit from further sub-headings or some other signposting to aid the reader.

- As response to referee 2, we no added a column in the tables 3-5 (variable nr) which we also use in the text to make navigation easier for readers. We hope that this is satisfactory.

Additionally, in general across the results I think the authors need to make the point that as this is a cross-sectional survey, the results are associations between variables rather than 'effect' of one variable on another, which intimates causality or temporal association.

- Yes, we agree. We revised wording in the results slightly and added this as limitation to the discussion section: “Finally, it is worth noting that this was a cross-sectional study and we can thus not make causal inferences about the relationships between variables. “

OTHER COMMENTS:
I feel that the discussion would benefit from a wider look at the literature on family involvement in care. Paediatrics in particular has a long history of involving families and carers, and there may be work there around the issue of involving patients' families in care. An example of this would be: Eichner et al (2012) 'Patient- and family-centered care and the paediatrician's role' Pediatrics,

129(2):394-404.

- We did have a look at the literature when writing this paper and while there are some interesting papers on family involvement we felt it was beyond the scope to discuss this in our paper as they talk about family involvement more generally – we could not find anything that looked at HCPs' attitudes towards family involvement in the safety-related behaviours we examined. There is a real paucity of research in this area which is why we wanted to undertake the study. Also family involvement in other areas of care (such as care planning etc) is likely to be viewed differently to involvement in preventing errors.

In general I feel this is a well written paper, that would just benefit from some additional detail in terms of the method, the survey tool used (given its focal role in the results and conclusions), and perhaps a wider discussion on some of the policy imperatives and other literature on the involvement of families in patient-centred care.

- Please see our responses to related comments on the development of the survey tool and review of the literature.

VERSION 2 – REVIEW

REVIEWER	Dr Christopher Vincent UCL Interaction Centre, England
REVIEW RETURNED	14-Aug-2014

GENERAL COMMENTS	I have read the reviewer comments and the revised paper. It remains a nice piece of work, although it is good to see the revisions. In terms of the content of my review, the changes are satisfactory. I would agree with the first referee that the paper is interesting and important. I would also agree that the method has been well-designed. There is a very minor typo on page 12, line 48 (double full stop). I would suggest that the other reviewers have addressed any concerns with the stats (e.g. question - does this paper require specialist statistical review?)