

BMJ Open

Predictors of healthcare professionals' attitudes towards family involvement in safety-relevant behaviours

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005549
Article Type:	Research
Date Submitted by the Author:	28-Apr-2014
Complete List of Authors:	Davis, Rachel; Imperial College London, Department of Surgery and Cancer Savvopoulou, Maria Shergill, Raman Shergill, Saman Schwappach, David
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research, Patient-centred medicine
Keywords:	Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

Peer review only

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	NA
		(d) If applicable, describe analytical methods taking account of sampling strategy	NA
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	8-10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	17-21 in tables
		(b) Report category boundaries when continuous variables were categorized	8-10,17-21
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-10,17-21
Discussion			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	4

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

1
2
3 **Predictors of healthcare professionals' attitudes towards family involvement in safety-relevant**
4 **behaviours**
5
6
7

8 **Authors and affiliations**
9

10 Davis R¹, Savvopoulou M¹, Shergill R², Shergill S³, Schwappach, D^{4,5}.
11

12
13 ¹ Centre for Patient Safety and Service Quality, Division of Surgery, 5th Floor Medical School
14 Building, Imperial College London, St Mary's Campus, Norfolk Place, London, W2 1PG.
15

16 ² Leicester Medical School, University Road, Leicester, LE1 9HN
17

18 ³ Hull York Medical School, University of York, North Yorkshire YO10 5DD
19

20 ⁴ Swiss Patient Safety Foundation. Asylstr. 77. 8032 Zurich, Switzerland.
21

22 ⁵ Institute of Social and Preventive Medicine (ISPM). University of Bern. Switzerland
23

24 Correspondence to: Rachel Davis. email: rachel.davis@imperial.ac.uk
25
26
27
28
29
30

31 **Word count:** 2985
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Abstract

Objective: To investigate predictors of doctors' and nurses' attitudes towards family involvement in two safety-relevant behaviours including asking the doctor/nurse to: 1) check the patient's medication, and; 2) wash their hands.

Design: A cross-sectional fractional factorial survey that assessed HCPs' attitudes towards family involvement in two error scenarios relating to hand hygiene and medication safety. Each survey comprised two randomised vignettes that described the potential error, how the family member communicated with the HCP about the error and how the HCP responded to the family member's question.

Setting: 5 hospitals in London and the Midlands

Participants: 160 HCPs (73 doctors; 87 nurses) aged between 21-65 years (mean: 37): 102 were female. The response rate was 77%

Outcome measures: HCP approval of family member's behaviour; HCP reaction to the family member; anticipated effects on the family member-HCP relationship; HCP support for being questioned asked about hand hygiene/medication; affective rating responses.

Results: HCPs supported family member's intervening but only 43% agreed that this would have positive effects on the family member/HCP relationship. Across vignettes and error scenarios the strongest predictors of attitudes were how the HCP (in the scenario) responded to the family member's questioning and whether an error actually occurred. Doctors (vs. nurses) provided systematically more positive affective ratings to the vignettes.

Conclusions: Important predictors of HCPs' attitudes towards family members' involvement in patient safety have been highlighted. In particular, a discouraging response from HCPs decreased support for family members being involved and had strong perceived negative effects on the family-member/HCP relationship.

Strengths and limitations of this study

- This is the first quantitative study to examine factors affecting doctors' and nurses' attitudes towards families questioning them about patient-related safety concerns.
- This paper highlights that the strongest predictors of attitudes were how the HCP (in the scenario) responded to the family member's questioning and whether an error actually occurred.
- We used experimental vignettes to assess important determinants of HCPs' attitudes but the ecological validity of the results remains to be established.
- Doctors and nurses were recruited from several sites across London, the Midlands and Yorkshire but the wider generalizability of the findings needs to be assessed.

1
2
3 **Acknowledgements:** We thank the research participants for their time in completing our survey.
4
5

6 **Contributors:** DS conceptualised the study and designed the survey instrument with the assistance of
7 RD. RD monitored data collection and entry for the survey and DS analysed data. Both RD and DS
8 drafted and revised the paper. RD is guarantor and affirms this is an honest and transparent account of
9 the study being reported; that no important aspects of the study have been omitted, and that; any
10 discrepancies from the study have been explained. MS, RS and SS collected the data and provided
11 feedback on the paper. All authors had full access to all of the data (including statistical reports and
12 tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data
13 analysis.
14
15
16
17
18

19 **Funding:** The Clinical Safety Research Unit is affiliated with the Centre for Patient Safety and
20 Service Quality at Imperial College Healthcare NHS Trust which is funded by the National Institute
21 of Health Research. The opinions expressed are those of the authors and do not necessarily reflect the
22 policies or views of the National Institute of Health Research. The NIHR played no role in the study
23 design; collection, analysis, and interpretation of data; writing of the manuscript; or the decision to
24 submit the article for publication. Researchers were independent of influence from the NIHR.
25
26
27
28
29

30 **Competing interests:** *"All authors have completed the Unified Competing Interest form at*
31 *www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author Rachel Davis)*
32 *and declare that (1) RD, MS, RS, SS, and DS have support from Imperial College London for the*
33 *submitted work; (2) have no relationships with companies that might have an interest in the submitted*
34 *work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships*
35 *that may be relevant to the submitted work and; (4) have no non-financial interests that may be*
36 *relevant to the submitted work"*
37
38
39
40
41
42

43 **Ethical approval:** The study was considered by the Chair of Hampstead's National Research Ethics
44 Committee and classified as exempt from review.
45
46

47 **Data sharing:** Informed consent to participate in the study was gained from all research participants.
48 The data presented in this manuscript are anonymised thus there is no risk of participant
49 identification. There is no additional data available.
50
51
52

53 **Competing interests:** None.
54
55
56
57
58
59
60

Introduction

Improving patient safety is an international priority in healthcare¹⁻³. Traditionally efforts to reduce preventable harm have targeted the practices and systems within healthcare organisations and the skills and behaviour of those delivering clinical care. More recently though, the contributions that patients can make to their safety has been highlighted⁴⁻⁷, with the last decade in particular seeing a surge of interest in this area^{6,8}. There are numerous opportunities throughout the care pathway for patients to help reduce their risk of healthcare harm^{4,9,10}. Monitoring and questioning the safety practice of healthcare professionals (HCPs) is one area in particular that holds promise¹¹. Patients have been shown to flag up safety problems (e.g. being given the wrong medication) that may otherwise go unnoticed¹² meaning that prompt action can then be taken to mitigate (potential) adverse effects.

In addition, to the patient themselves, the role of family members in monitoring safe practice, can be equally important. In settings where patients are especially vulnerable and unable to look after themselves (e.g. paediatrics and care of the elderly) families are often the patients primary source of strength and support thus their role in ensuring safety takes on a particularly important role. Despite the important contributions that family members could make, it is currently not clear what their attitudes towards involvement would be and/or their willingness to voice any safety-related concerns. However, drawing from the wider literature on patients themselves, evidence strongly suggests patients find it harder to ask questions that could be perceived as challenging the clinical abilities of HCPs (e.g. *'have you washed your hands?'*) than those related to more general aspects of their recovery (*'how long will I be in hospital for?'*)^{6,11,13-17}. Fear of reprisal, being uncomfortable/anxious about asking, undermining HCPs' clinical abilities and adversely affecting the HCP-patient relationship are key reasons for patients' reluctance to participate¹⁸⁻²¹. To improve participatory levels research has shown that by HCPs giving patients encouragement to 'speak-up' about safety-related issues a significant positive impact on their willingness to be involved can be observed^{11,13,14,22}. It is likely (but yet to be empirically explored) that HCP encouragement could pose analogous effects on family members' willingness to ask safety-related questions. To date however, the extent to which HCPs would support such questioning from patient's families is unknown. Gaining this understanding could be critical to the successful engagement of families in promoting safety and could help to explain why HCPs may support such involvement in some situations but not others.

In previous research we conducted in Switzerland and the UK we used vignettes to explore HCPs' attitudes towards patient involvement in two different error scenarios: poor hand hygiene of the HCP and incorrect medication for the patient^{23,24}. We found that several factors influenced HCPs' level of support for being questioned. Most notably, HCPs viewed patient involvement more favourably if the error described in the scenario actually occurred (i.e. the HCP had not cleaned their hands before

1
2
3 treating the patient), if the patient posed the question in a polite vs. challenging way and if the HCP
4 responded in a helpful and reassuring manner (i.e. the HCP apologised and cleaned their hands). In
5 the present paper we aim to build on our previous research and to address the apparent gap in the
6 evidence-base by examining HCPs' attitudes towards family involvement in safety. Our specific
7 research question was: what are the predictors of doctors' and nurses' attitudes towards family
8 members questioning HCPs: 1) about the HCPs' HH, and; 2) about the patient's medication?
9
10
11

12 13 **Methods**

14 15 **Design**

16
17
18 A cross-sectional factorial survey containing vignettes was employed. In total 8 different surveys
19 were used, each of which comprised vignettes on two types of potential errors; a possible medication
20 error and potentially missed hand disinfection. Each vignette consisted of 7 dichotomous variables
21 (factors) each with two levels that were chosen in accordance with previous research and apriori
22 hypotheses²³⁻²⁵. Three factors in the vignettes related to the family member (relation to the patient
23 (e.g. parent, daughter), sex, and the way in which they questioned the HCP in the scenario), two
24 related to the HCP (occupation and reaction to the family member's question), and two were error-
25 related (correct/false attribution of error and if the error was witnessed by another HCP). The seven
26 variables generated 128 possible combinations. Using experimental design software this was reduced
27 to 8 combinations of random pairings of the two clinical scenarios in a fractional main effects design²⁶
28 (see Box 1 for examples of vignettes).
29
30
31
32
33
34

35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
Box 1 here

39 40 **Measures**

41
42 A 22-item survey was developed to assess HCPs' attitudes towards family involvement in two
43 different error scenarios, one relating to the hand hygiene of the HCP and the other relating to the
44 patient's medication (11 items on each). Eight items (4 on each error scenario) assessed HCPs' level
45 of agreement with 4 attitudinal statements about the scenario: 1) I approve of the family member's
46 behaviour; 2) the HCP responded in the right manner; 3) the situation would have predominantly
47 positive effects on the family member-HCP relationship, and; 4) I would as a HCP support the family
48 member in asking me about my hand hygiene/the patient's medication. A 7-point Likert response
49 scale was used ranging from 'strongly disagree' to 'strongly agree' (higher scores indicating more
50 favourable responses).
51
52
53
54
55
56
57
58
59
60

1
2
3 Fourteen items (7 on each scenario) explored HCPs 'affective' ratings of the family member
4 intervening (i.e. how they would feel if they were in the situation described in the scenario and were
5 questioned by a patient's family member). HCPs were asked: '*If you were the HCP, how would the*
6 *described situation be for you?*'. Responses were presented as 7 semantic differentials: 1) bad – good;
7
8 2) difficult – easy; 3) confrontational – not confrontational at all; 4) uncomfortable – comfortable; 5)
9 not helpful at all – very helpful; 6) very embarrassing – not embarrassing at all; 7) very challenging –
10 not challenging at all. A 7-point response scale was used with the semantic differentials serving as
11 anchor labels (higher scores indicating more favourable responses).
12
13
14
15

16 Prior to data collection the survey was tested on 20 HCPs (12 doctors and 8 nurses) and minor
17 iterations were made to ensure face validity and comprehension of survey items.
18
19

20 **Participants**

21
22
23 Data were collected from doctors and nurses from five hospitals in London (N=3), Leicester (N=1)
24 and York (N=1) between October 2013-March 2014. HCPs were approached face-face on the hospital
25 wards, provided with an explanation of the study and asked for their consent to participate.
26
27

28 **Data analysis**

29
30
31 Data were analysed using STATA Version 13. Mean scores for survey items were compared
32 according to the error scenario and vignettes attributes. Significant differences were analysed using T
33 tests. Scale reliability was computed (Cronbach's Alpha) for the affective rating items for each error
34 scenario (N=7) and the mean scale score was calculated. Multiple regression analyses were performed
35 to examine the effect of vignette attributes and participants' characteristics (entered as predictor
36 variables) on attitudes towards family member's involvement. Sample size was calculated based on
37 recommendations for the use of regression analysis in behavioural research^{27,28}. Five regression
38 models were conducted for each error scenario (10 in total) relating to each of our key outcome
39 measures: 1) approval of family member's behavior; 2) approval of HCPs response to the family
40 member; 3) support for being asked as a HCP; 4) positive effects on the family member-HCP
41 relationship, and; 5) the overall mean affective rating score. Chow-tests were performed to test if the
42 coefficients in the regression models for the medication error and hand hygiene scenarios were
43 significantly different or whether the models could be pooled. Data were screened for
44 multicollinearity and to ensure parametric assumptions were met. All tests were two-sided. We
45 considered $p < 0.05$ to be significant.
46
47
48
49
50
51
52
53
54

55 **Results**

Participant characteristics

In total, 209 HCPs were approached and 160 HCP completed the survey (77% response rate) 73 (46%) respondents were doctors, 87 (54%) were nurses, aged between 21-65 years (mean = 37 years; SD = 10.4). 102 (64%) responders were female. HCPs that declined participation did so because they said they were too busy (N=40) or did not want to take part in the study (N=9).

Findings in relation to error frame

Across all scenarios, HCPs were supportive of the family member intervening (i.e. questioning the HCP) (mean approval score=5.8, CI 5.6-5.9). However, only 43% agreed that such behaviour would have positive effects on the family member-HCP relationship (responders with ratings >4). There were no significant differences in HCPs' responses to family members intervening in the medication error frame compared to the hand hygiene frame (Table 1).

Table 1 here

Affecting ratings scores

There was high internal consistency between HCPs' affective ratings scores (Cronbach's Alpha = 0.90) thus composite scores were calculated (i.e. overall mean score of the seven affective ratings per person). There were no significant differences in the affective ratings or in the composite score in the medication error frame versus the hand hygiene frame. Doctors provided systematically more positive affective ratings as compared to nurses (Table 2).

Table 2 here

Correlations between affective rating scores and key outcome measures

Pearson's correlations revealed associations between HCPs' mean affective rating scores (composite measure) and responses to the 4 attitudinal judgments: I approve of the family members behaviour ($r=0.08$, $p=0.18$); support for being asked as a HCP ($r=0.10$, $p=0.07$); the HCP responded in the correct manner ($r=0.12$, $p=0.03$); the situation would have positive effects on the family member-HCP relationship ($r=0.26$, $p<0.001$). Thus, HCPs were more likely to expect positive effects on the family member-HCP relationship if they also perceived the HCP behavior more favorably.

Results of the regression analyses

1
2
3 In multiple regression analyses, the impact of vignette attributes and respondents' characteristics on
4 each of the survey questions were modelled. The results of the Chow tests revealed that the
5 coefficients of the medication error and the hand hygiene models were not equal for three out of five
6 outcomes measures (approval of behaviour; support of being asked as a HCP; affective rating
7 composite score). Based on these findings we estimated separate models for the different error frames.
8
9 The results of the regression analyses are displayed in Tables 3-5.
10
11

12
13 Tables 3-5 here
14
15

16 The single most important predictor variable in all models was the described HCP response to the
17 family member intervening. A discouraging HCP response (as compared to an encouraging response)
18 decreased approval and support of family member's behaviour, affective ratings and had strong
19 negative effects on the anticipated HCP-family member relationship. In both error frames, HCP
20 reactions to the family member's behaviour had large effects on respondents' evaluations of whether
21 the HCP responded in the right manner - a discouraging reaction was clearly judged negatively by
22 participants. The hypothetical family member's sex played a role in the evaluation of the interactions
23 with staff (HCP response to being questioned and effects on the HCP-family member relationship)
24 with male family members' interventions being seen less positive by responders. Family member's
25 sex contributed considerably to HCP's affective ratings but with opposite directions in the medication
26 and hand hygiene frames. Irrespective of vignette attributes, affective ratings were more positive
27 when the family member intervening was a male in the hand hygiene frame while they were higher
28 for female family members in the medication error scenario.
29
30
31
32
33
34
35

36
37 Whether the family member intervening was a daughter/son of a senior patient or mother/father of a
38 hospitalized child had only unsystematic and rather small effects.
39
40

41 When family members were described as intervening in a challenging rather than an inquiring way
42 this had only negative effects on approval and support of the behaviour in the medication error
43 frames.
44
45

46 The profession of the HCP involved in the interaction with the family member impacted on the
47 evaluations of the medication errors frames: The behaviour was more likely to be approved and seen
48 as positively affecting the relationship in scenarios in which the family member intervened towards a
49 doctor as compared to a nurse.
50
51
52

53
54 The attribution of error was an important predictor in the hand hygiene models in particular. A false
55 attribution of missed hand hygiene decreased approval and support of the behaviour and also had
56
57
58
59
60

1
2
3 negative effects on the anticipated HCP-family member relationship. A false attribution of error had
4 positive effects on the affective ratings in the medication error frame.
5
6

7 Whether the situation was witnessed by another HCP had only significant effects on the affective
8 ratings of the medication error frame. The family member's behaviour was perceived less positive
9 when the situation was witnessed by coworkers.
10
11

12 Nurses as compared to doctors were significantly more likely to approve of the family member's
13 behaviour (in the hand hygiene scenarios) and support the family member (both error frames).
14 However, even after adjusting for vignette characteristics, doctors were more likely to provide higher
15 affective ratings as compared to nurses. Other respondent's characteristics had only unsystematic and
16 marginal effects on vignette ratings.
17
18
19
20

21 Discussion

22 This experimental vignette study set out to explore factors that influence HCPs' attitudes towards
23 family member's involvement in two safety-relevant areas; asking HCPs about their hand hygiene and
24 checking patients' medication. To our knowledge, this is the first study into the acceptance of family
25 members' intervening towards the safety of their loved ones in hospital. Overall, we found a high
26 level of support and approval for families intervening among surveyed HCPs in both error scenarios.
27 However, over all described situations 60% disagreed that the family member's behaviour would have
28 positive effects on the relationship with the HCP. Across vignette attribute specifications, there were
29 no differences between respondents' attitudes towards the hand hygiene and the medication error
30 frames. Two factors in particular appear to have a strong effect on attitudes – correct attribution of the
31 error and how the HCP reacted to the family member's involvement. Doctors as compared to nurses
32 provided systematically more positive affective ratings to the vignettes. In particular, they rated the
33 hypothetical situations as easier and more comfortable to manage and as less embarrassing.
34
35
36
37
38
39
40
41
42

43 We found some important differences to our previous studies on HCPs' acceptance of patient
44 involvement in safety^{23,24}. First, respondents' evaluations of the vignettes were only slightly and
45 unsystematically affected by how the family member intervened (challenging vs. inquiring).
46 Conversely however, our previous research revealed that patient behaviour was a strong predictor of
47 HCPs' approval; a finding also reflected in the wider literature. Garcia-Williams reported that HCPs
48 level of support in patients asking them about their hand hygiene would 'depend' on how they were
49 asked¹⁵. Second, HCPs in previous studies were much more positive about patient engagement in
50 medication safety and were more reluctant about involvement in hand hygiene. In this study, we
51 found some differences in attributes affecting outcomes measures (e.g., approval and affective
52 ratings), but only minor differences in overall level of support between medication error and hand
53
54
55
56
57
58
59
60

1
2
3 hygiene frames. Taken together, these results could potentially suggest that HCPs actually view
4 family involvement differently as it involves a different dynamic to the patient interacting with them.
5 Family engagement in safety seems to trigger less emotionally and strong responses by HCPs. The
6 fact, that the affective ratings were not as strong as in our previous studies also lends some support to
7 this hypothesis.
8
9

10
11 Another apparent difference between this study and prior research into HCP attitudes is that doctors in
12 our study provided more favorable affective ratings than nurses. In previous research, including those
13 using similar vignettes, nurses were not only more willing to support being questioned themselves
14 about safety-related issues by patients^{23,24,29}, they also reported more positive affective ratings^{23,24}.
15 We can only speculate on the reasons for this finding. One explanation may be that doctors less often
16 experience situations in which family members question or challenge them. As a consequence, they
17 may underestimate the difficulty of this situation and emotionally demanding interactions.
18
19
20
21
22

23 This study is the first of its kind to provide insight into HCPs' acceptance of family members
24 questioning them about hand hygiene and medication safety-related concerns. A main strength is that
25 we used an experimental design to systematically manipulate factors and observe the effects of this
26 manipulation, something we would not be able to control for in observational studies. As we used the
27 same factors and frames as in our previous studies we can directly explore areas of agreement and
28 differences between HCPs' attitudes towards patients' and family members' involvement in patient
29 safety. Finally, the response rate to the survey is reasonably good, in particular for a HCP sample.
30
31
32
33
34

35 The main limitation of our study is that we assessed attitudes and this is not always reflective of
36 behaviour. We thus do not know how participants in our study would in reality respond to families
37 engaging for the safety of their loved ones. We used "true life" vignettes to improve and assimilate
38 respondents' conceptions of family behaviour but the responses are still biased by "hypotheticality".
39 The sample is relatively small and the wider generalisability of our results needs to be assessed in
40 future studies. Due to design and sample size reasons, we could not model interactions of vignette
41 attributes though these may be important for judgments about the scenarios.
42
43
44
45
46

47 This study serves only as an initial step into research in family engagement in safety. Today, very
48 little is known about family members attitudes and feelings about engagement, let alone strategies to
49 encourage involvement and whether families would be more willing to act on their loved ones behalf
50 than if they themselves were a patient in hospital. Studies could use a similar design to explore family
51 members' attitudes towards involvement - this would be an interesting parallel and is yet to be
52 explored. Also, little is known about the benefits and adverse effects of family involvement. While
53 family members questioning HCPs could result in positive effects (i.e. improved safety), the potential
54 adverse consequences of involving them remain unknown, e.g. it could potentially heighten anxiety,
55
56
57
58
59
60

1
2
3 placing inappropriate responsibility on them when they are already worried about their loved, or it
4 could make them fear if they do not question HCPs the patient will be at increased risk. It may also
5 create tensions in their relationship with HCPs - though our results do not seem to indicate this.
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Funding

This work was funded by the NIHR

Contributorship Statement

DS conceptualised the study and designed the survey instrument with the assistance of RD. RD monitored data collection and entry for the survey and DS analysed data. Both RD and DS drafted and revised the paper. RD is guarantor and affirms this is an honest and transparent account of the study being reported; that no important aspects of the study have been omitted, and that; any discrepancies from the study have been explained. MS, RS and SS collected the data and provided feedback on the paper. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Competing Interests

None

Data Sharing Statement

There is no additional data available.

References

1. World Health Organisation (WHO). Quality of Care: Patient Safety. Fifty-fifth World Health Assembly, 2002. <http://www.who.int/patientsafety/worldalliance/ea5513.pdf?ua=1>
2. WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge Clean Care is Safer care, 2009
http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf?ua=1
3. WHO. Global priorities for research in patient safety (first edition). The Research Priority Setting Working Group, 2008.
http://www.who.int/patientsafety/research/priorities/global_priorities_patient_safety_research.pdf
4. Vincent C, Coulter A. Patient safety: what about the patient? Quality and Safety in Healthcare, 2002; 11: 76-80.

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
5. Coulter A, Ellins J. Patient-focused interventions: A review of the evidence. Chapter 4 'Improving patient safety', pgs 143-178. Health Foundation, 2006.
 6. Schwappach D. Engaging patients as vigilant partners in safety. A systematic review. Medical Care Research and Review, 2010; 67:2: 119-148
 7. Lawton R, Armitage G. The role of the patient in clinical safety. Health Foundation, 2012.
 8. WHO. Exploring patient participation in reducing healthcare-related safety risks. WHO, 2013 http://www.euro.who.int/_data/assets/pdf_file/0010/185779/e96814.pdf
 9. Davis R, Sevdalis N, Jacklin R, Vincent C. An examination of opportunities for the active patient in improving patient safety. Journal of Patient Safety, 2012; 8:1:36-43.
 10. Davis R, Vincent C, Murphy M. Blood transfusion safety: The potential role of the patient. Transfusion Medicine Reviews, 2011; 25:1:12-23.
 11. Davis R, Sevdalis N, Vincent C. Patient involvement in patient safety- How willing are patients to participate? BMJ Quality and Safety, 2011; 20:108-114.
 12. Unruh KT, Pratt W. Patients as actors: the patient's role in detecting, preventing, and recovering from medical errors. International Journal of Medical Informatics 2007; 76(Suppl 1):S236-44.
 13. Davis R, Koutantji M, Vincent C. How willing are patients to question healthcare staff on issues related to the quality and safety of their healthcare? An exploratory study, Quality and Safety in Health Care, 2008. 17; 90-96.
 14. Longtin, Y et al. 2009. Patients' beliefs and perceptions of their participation to increase healthcare worker compliance with hand hygiene. Infection Control and Hospital Epidemiology, 2009; 30:9: 830-839.
 15. Garcia-Williams A, Brinsley-Rainisch K, Schille S, Sinkowitz-Cochran R. To ask or not to ask? The results of a formative assessment of a video empowering patients to ask their health care providers to perform hand hygiene. Journal of Patient Safety, 2010; 6:2: 80-85.
 16. Hibbard J, Peters E, Slovic P, Tusler M. 2005). Can patients be part of the solution? Views on their role in preventing medical errors. Medical Care Research and Review 2005; 62: 601-616.
 17. Marella, W. M. et al. (2007). Healthcare consumers' inclination to engage in selected patient safety practices: a survey of adults in Pennsylvania. Journal of Patient safety, 3, 184-189.
 18. Pittet D, Panesar SS, Wilson K, et al. Involving the patient to ask about hospital hand hygiene: a National Patient Safety Agency feasibility study Journal of Hospital Infection 2011; 77: 299-303.
 19. Ottum A, Sethi AK, Jacobs EA, Zerbal S, Gaines ME, Safdar N. Do patients feel comfortable asking healthcare workers to wash their hands? Infection Control and Hospital Epidemiology, 2012; 33:12:1282-1284

- 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
 - 16
 - 17
 - 18
 - 19
 - 20
 - 21
 - 22
 - 23
 - 24
 - 25
 - 26
 - 27
 - 28
 - 29
 - 30
 - 31
 - 32
 - 33
 - 34
 - 35
 - 36
 - 37
 - 38
 - 39
 - 40
 - 41
 - 42
 - 43
 - 44
 - 45
 - 46
 - 47
 - 48
 - 49
 - 50
 - 51
 - 52
 - 53
 - 54
 - 55
 - 56
 - 57
 - 58
 - 59
 - 60
20. Michealson K, Sanders JL, Zimmer SM, Bump GM. Overcoming patient barriers to discussing physician hand hygiene: do patients prefer electronic reminders to other methods? *Infection Control and Hospital Epidemiology*, 2013; 34:9:929-934.
21. Julian K, Subramanian K, Brumbach A, Whitener CJ. Attitudes of healthcare workers and patients towards individualised hand hygiene reminders. *Infection Control and Hospital Epidemiology*, 2008; 29:8:781-782.
22. WHO Alliance for Patient Safety Hand Hygiene Survey Results from Phase One October 2007 http://www.who.int/patientsafety/hand_hygiene_survey.pdf
23. Davis R, Briggs M, Arora S, Schwappach D. Predictors of healthcare professionals' attitudes towards involvement in safety-related behaviours. *Journal of Evaluation and Clinical Practice*, 2014; 20:1:12-9.
24. Schwappach D, Davis R, Frank O. A vignette study to examine healthcare professionals' attitudes toward patient involvement in error prevention. *Journal of Evaluation and Clinical Practice*, 2013;19:5:840-8
25. Schwappach DL, Hochreutener MA, Wernli M. Oncology nurses' perceptions about involving patients in the prevention of chemotherapy administration errors. *Oncol Nurs Forum* 2010; 37:2:E84-E91.
26. Bradley M. Users manual for SPEED. version 2.1 stated preference editor and designer. The Hague: Hague Consulting Group; 1991.
27. Park C, Dudycha A. A cross-validation approach to sample size determination. *Journal of the American Statistical Association*, 1974; 69: 214-218.
28. Pedhazur EJ. Multiple regression in behavioral research. Harcourt Brace: Orlando, FL, 1997.
29. Davis RE, Sevdalis N, Vincent CA. Patient involvement in patient safety: the health-care professional's perspective. *Journal of Patient Safety*, 2012;8:4:182-8

Tables and boxes

Box 1: Example vignettes

Factor	Levels with coding
A Family member's sex	0: Female 1: Male
B Relation to patient	0: Parent to patient 1: Child of patient
C Situation witnessed	0: No, patient and HCP are alone 1: Yes, event is witnessed by other HPC
D Staff occupation	0: Nurse 1: Doctor
E Patient's behavior	0: Inquiring 1: Challenging
F Attribution of error	0: True, HCP did make an error 1: False, HCP did not make an error
G Staff response	0: Encouraging 1: Discouraging

Error scenario 1, vignette A₀B₀C₁D₁E₀F₀G₁

Mrs Smith is mother to a five year old boy. Mrs Smith's son has been in hospital for a few days. He had a complicated appendectomy. Mrs Smith is present at hospital daily to watch after her son. During the morning several doctors and nurses enter the room. A doctor inspects the wound dressing of Mrs Smith's son. Mrs Smith looks anxious and asks: *excuse me, shouldn't you need to wash your hands?* As it is a very busy morning the doctor had in fact forgot to wash his hands. The doctor rolls his eyes and disinfects his hands using alcohol gel.

Error scenario 2, vignette A₁B₀C₀D₁E₁F₀G₀

Mr Brown is father to a five year old boy. Mr Brown's son has been in hospital for a number of days. He is suffering from severe heart problems. Mr Brown is present at hospital daily to watch after his son. His son has been prescribed several drugs. Early this morning, the nurse gave the medication to Mr Brown and instructed him that his son should take them with breakfast. Later on in the morning a doctor enters the room. The doctor asks Mr Brown's son how he is doing. Mr Brown looks angry and states: *Can you please check these red tablets. I do not think these are meant to be for my son!* The doctor had been very busy when writing prescriptions yesterday and had been interrupted several times. The doctor checks the medication against the chart and says: *'oh yes it is very good that you ask. I am really sorry it seems that your son indeed has been given the wrong medication. Your prescription should not have changed.*

Note: letters in Box 1 indicate factors and numbers in superscripts represent the levels

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Table 1. Results in relation to error frame (N=160)

Outcome measure (survey questions)	Error scenario*		p
	Hand hygiene Mean, [CI]	Medication error Mean, [CI]	
I approve of the family member's behaviour	5.9 [5.6,6.1]	5.7 [5.4,5.9]	0.2589
The HCP responded in the right manner	4.8 [4.5,5.2]	4.7 [4.3,5.0]	0.5015
The situation would have predominantly positive effects on the caregiver-HCP relationship	4.0 [3.7,4.4]	3.8 [3.5,4.2]	0.3852
I would as a HCP support the caregiver asking me	6.0 [5.8,6.2]	6.0 [5.8,6.2]	0.9650

**Level of agreement was measured on a 7-point Likert response scale with higher numbers indicating higher levels of agreement.*

Table 2. Results of affective ratings scores (N=160)

Affective items	Mean rating* [CI]			p
	Total	Doctors	Nurses	
Bad-Good	3.6 [3.4,3.8]	4.0 [3.7,4.2]	3.4 [3.1,3.7]	0.0041
Difficult-Easy	3.7 [3.5,3.9]	4.1 [3.8,4.3]	3.3 [3.1,3.6]	0.0001
Confrontational -Not confrontational	3.9 [3.7,4.1]	4.2 [3.9,4.5]	3.7 [3.4,4.0]	0.0243
Not helpful - Very helpful	4.7 [4.6,4.9]	4.8 [4.6,5.0]	4.7 [4.4,4.9]	0.4661
Very embarrassing-Not embarrassing	3.8 [3.5,4.0]	4.3 [4.0,4.6]	3.3 [3.0,3.6]	<0.0001
Challenging -Not challenging	4.1 [3.9,4.3]	4.4 [4.1,4.7]	3.8 [3.5,4.1]	0.0040
Very uncomfortable-Comfortable	3.6 [3.4,3.8]	4.1 [3.8,4.3]	3.2 [2.9,3.5]	<0.0001
Composite, affective score**	3.9 [3.8,4.1]	4.2 [4.0,4.5]	3.6 [3.4,3.8]	0.0001
<p>*A 7-point response scale was used with the semantic differentials serving as anchor labels (higher scores indicating more favourable responses)</p> <p>** Mean over the seven ratings per person</p>				

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Table 3. Results of multiple regression analyses (N=160)

	Approval of family member’s behaviour						The HCP responded in the right manner					
	HH Error Vignettes			Medication Error vignettes			HH Error Vignettes			Medication Error vignettes		
	Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p
Vignette attributes												
Family member gender (1=male)	0.047	-0.383,0.477	0.830	-0.042	-0.422,0.337	0.825	-0.779	-1.321,-0.236	0.005	-0.403	-0.881,0.075	0.098
Relation to patient (1=daughter/son of patient)	-0.251	-0.679,0.177	0.249	-0.436	-0.813,-0.058	0.024	0.232	-0.308,0.772	0.398	0.015	-0.462,0.491	0.952
Situation witnessed (1=yes)	0.056	-0.385,0.496	0.803	-0.319	-0.692,0.053	0.092	-0.072	-0.627,0.483	0.799	0.299	-0.171,0.769	0.210
Staff occupation (1=doc)	0.110	-0.316,0.535	0.611	0.429	0.037,0.820	0.032	0.226	-0.310,0.763	0.406	0.621	0.126,1.115	0.014
Family member behavior (1=challenging)	-0.384	-0.808,0.040	0.076	-1.362	-1.737,-0.987	0.000	0.386	-0.149,0.920	0.156	-0.210	-0.683,0.263	0.382
Attribution of error (1=false)	-1.033	-1.471,-0.594	0.000	-0.683	-1.059,-0.306	0.000	-0.779	-1.331,-0.226	0.006	-0.422	-0.897,0.053	0.081
Staff response (1=discouraging)	-0.583	-1.013,-0.153	0.008	-0.756	-1.143,-0.370	0.000	-2.799	-3.341,-2.257	0.000	-3.119	-3.606,-2.632	0.000
Respondents’ characteristics												
Doctor or nurse (1=nurse)	0.520	0.040,1.000	0.034	0.083	-0.340,0.506	0.699	0.498	-0.107,1.103	0.106	0.355	-0.179,0.889	0.191
Age, years	0.008	-0.038,0.054	0.726	-0.034	-0.075,0.006	0.097	-0.024	-0.082,0.034	0.410	0.010	-0.041,0.062	0.686
Sex (1=female)	0.019	-0.488,0.525	0.942	-0.092	-0.539,0.355	0.686	-0.731	-1.370,-0.092	0.025	-0.343	-0.907,0.220	0.231
Years of experience, years	-0.016	-0.065,0.034	0.534	0.048	0.005,0.092	0.030	0.011	-0.052,0.073	0.739	-0.033	-0.088,0.022	0.237
constant	6.449	4.875,8.022	0.000	8.010	6.741,9.278	0.000	7.596	5.612,9.580	0.000	6.261	4.661,7.861	0.000
R-sqr	0.229			0.400			0.467			0.581		
overall model p	<0.001			<0.001			<0.001			<0.001		

Review only

Table 4. Results of multiple regression analyses (N=160)

	Positive effects on the family member/HCP relationship						Support for being asked as a HCP					
	HH Error Vignettes			Medication Error vignettes			HH Error Vignettes			Medication Error vignettes		
	Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p
Vignette attributes												
Family member gender (1=male)	-0.523	-1.072,0.026	0.062	-0.596	-1.073,-0.120	0.015	-0.308	-0.676,0.060	0.101	-0.120	-0.508,0.267	0.540
Relation to patient (1=daughter/son of patient)	0.321	-0.226,0.867	0.248	0.038	-0.437,0.512	0.875	0.389	0.023,0.756	0.038	-0.195	-0.581,0.191	0.320
Situation witnessed (1=yes)	0.045	-0.517,0.607	0.874	0.132	-0.336,0.600	0.577	0.293	-0.084,0.669	0.127	-0.186	-0.566,0.195	0.336
Staff occupation (1=doc)	0.050	-0.493,0.593	0.856	0.760	0.267,1.252	0.003	0.395	0.031,0.759	0.034	0.072	-0.329,0.472	0.724
Family member behavior (1=challenging)	-0.127	-0.668,0.413	0.642	-0.454	-0.926,0.017	0.059	0.225	-0.138,0.587	0.223	-0.432	-0.815,-0.048	0.028
Attribution of error (1=false)	-0.943	-1.502,-0.384	0.001	0.098	-0.375,0.571	0.683	-0.725	-1.100,-0.350	0.000	0.162	-0.223,0.547	0.408
Staff response (1=discouraging)	-2.245	-2.794,-1.697	0.000	-2.420	-2.905,-1.934	0.000	-0.509	-0.877,-0.141	0.007	-0.379	-0.774,0.016	0.060
Respondents' characteristics												
Doctor or nurse (1=nurse)	0.400	-0.212,1.012	0.199	0.172	-0.360,0.703	0.524	0.490	0.079,0.900	0.020	0.580	0.148,1.013	0.009
Age, years	-0.004	-0.063,0.055	0.897	-0.003	-0.054,0.048	0.915	-0.007	-0.047,0.032	0.711	0.005	-0.037,0.046	0.821
Sex (1=female)	-0.377	-1.024,0.269	0.251	-0.135	-0.696,0.427	0.636	-0.139	-0.573,0.294	0.527	-0.153	-0.610,0.303	0.508
Years of experience, years	-0.011	-0.074,0.052	0.733	-0.019	-0.074,0.035	0.488	-0.005	-0.048,0.037	0.802	0.003	-0.041,0.048	0.893
constant	6.043	4.035,8.051	0.000	5.374	3.780,6.968	0.000	6.297	4.950,7.644	0.000	6.135	4.839,7.431	0.000
R-sqr	0.377			0.484			0.255			0.124		
overall model p	<0.001			<0.001			<0.001			0.042		

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Table 5. Results of multiple regression analyses (N=160)

	Affective ratings scores					
	Hand hygiene vignettes			Medication error vignettes		
	Coeff	95% CI	p	Coeff	95% CI	p
Vignette attributes						
Family member gender (1=male)	0.786	0.414,1.159	0.000	-0.846	-1.198,-0.493	0.000
Relation to patient (1=daughter/son of patient)	0.015	-0.356,0.386	0.935	0.415	0.064,0.767	0.021
Situation witnessed (1=yes)	0.179	-0.203,0.560	0.356	-0.369	-0.715,-0.022	0.037
Staff occupation (1=doc)	-0.048	-0.417,0.321	0.797	0.170	-0.195,0.534	0.359
Family member behavior (1=challenging)	0.108	-0.260,0.475	0.564	-0.158	-0.506,0.191	0.374
Attribution of error (1=false)	-0.336	-0.716,0.044	0.083	1.288	0.938,1.638	0.000
Staff response (1=discouraging)	-1.062	-1.435,-0.690	0.000	-0.592	-0.952,-0.233	0.001
Respondents' characteristics						
Doctor or nurse (1=nurse)	-0.525	-0.941,-0.109	0.014	-0.359	-0.753,0.034	0.073
Age, years	0.025	-0.015,0.065	0.226	0.017	-0.021,0.055	0.378
Sex (1=female)	-0.113	-0.552,0.327	0.613	-0.327	-0.743,0.089	0.122
Years of experience, years	-0.019	-0.062,0.024	0.375	-0.012	-0.052,0.029	0.572
constant	3.772	2.408,5.136	0.000	3.824	2.644,5.005	0.000
R-sqr	0.320			0.439		
overall model p	<0.001			<0.001		

Review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

For peer review only

BMJ Open

Predictors of healthcare professionals' attitudes towards family involvement in safety-relevant behaviours: A cross-sectional factorial survey study

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2014-005549.R1
Article Type:	Research
Date Submitted by the Author:	31-Jul-2014
Complete List of Authors:	Davis, Rachel; Imperial College London, Department of Surgery and Cancer Savvopoulou, Maria; Imperial College London, Shergill, Raman; Leicester Medical School, Shergill, Saman; York Medical School, Schwappach, David; Swiss Patient Safety Foundation,
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Health services research, Patient-centred medicine
Keywords:	Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7 **Predictors of healthcare professionals' attitudes towards family**
8 **involvement in safety-relevant behaviours: A cross-sectional factorial**
9 **survey study**
10
11
12

13
14 **Authors and affiliations**
15

16 Davis R¹, Savvopoulou M¹, Shergill R², Shergill S³ Schwappach, D^{4,5}
17
18
19

20
21 ¹ Centre for Patient Safety and Service Quality, Division of Surgery, 5th Floor Medical School
22 Building, Imperial College London, St Mary's Campus, Norfolk Place, London, W2 1PG.
23

24 ² Leicester Medical School, University Road, Leicester, LE1 9HN

25 ³ York Medical School, University of York, North Yorkshire YO10 5DD

26 ⁴ Swiss Patient Safety Foundation. Asylstr. 77. 8032 Zurich, Switzerland.
27

28 ⁵ Institute of Social and Preventive Medicine (ISPM). University of Bern. Switzerland
29
30

31 Correspondence to: Rachel Davis. email: rachel.davis@imperial.ac.uk
32
33
34
35
36
37
38

39 **Word count:** 3351
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Abstract

Objectives: To investigate predictors of healthcare professionals (HCPs) attitudes towards family involvement in safety-relevant behaviours.

Design: A cross-sectional fractional factorial survey that assessed HCPs' attitudes towards family involvement in two error scenarios relating to hand hygiene and medication safety. Each survey comprised two randomised vignettes that described the potential error, how the family member communicated with the HCP about the error and how the HCP responded to the family member's question.

Setting: 5 teaching hospitals in London, the Midlands and York. HCPs were approached on a range of medical and surgical wards.

Participants: 160 HCPs (73 doctors; 87 nurses) aged between 21-65 years (mean: 37): 102 were female.

Outcome measures: HCP approval of family member's behaviour; HCP reaction to the family member; anticipated effects on the family member-HCP relationship; HCP support for being questioned about hand hygiene/medication; affective rating responses.

Results: HCPs supported family member's intervening (88%) but only 41% agreed this would have positive effects on the family member/HCP relationship. Across vignettes and error scenarios the strongest predictors of attitudes were how the HCP (in the scenario) responded to the family member and whether an error actually occurred. Doctors (vs. nurses) provided systematically more positive affective ratings to the vignettes.

Conclusions: Important predictors of HCPs' attitudes towards family members' involvement in patient safety have been highlighted. In particular, a discouraging response from HCPs decreased support for family members being involved and had strong perceived negative effects on the family-member/HCP relationship.

Strengths and limitations of this study

- This is the first quantitative study to examine factors affecting doctors' and nurses' attitudes towards families questioning them about patient-related safety concerns.
- This paper highlights that the strongest predictors of attitudes were how the HCP (in the scenario) responded to the family member's questioning and whether an error actually occurred.
- We used experimental vignettes to assess important determinants of HCPs' attitudes but the ecological validity of the results remains to be established.
- Doctors and nurses were recruited from several sites across London, the Midlands and Yorkshire but the wider generalizability of the findings needs to be assessed.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Introduction

Improving patient safety is an international priority in healthcare¹⁻³. Traditionally efforts to reduce preventable harm have targeted the practices and systems within healthcare organisations and the skills and behaviour of those delivering clinical care. More recently though, the contributions that patients can make to their safety have been highlighted⁴⁻⁷, with the last decade in particular seeing a surge of interest in this area^{6,8}. There are numerous opportunities throughout the care pathway for patients to help reduce their risk of healthcare harm^{4,9,10}. Monitoring and questioning the safety practice of healthcare professionals (HCPs) is one area in particular that holds promise¹¹. Patients have been shown to flag up safety problems (e.g. being given the wrong medication) that may otherwise go unnoticed¹² meaning that prompt action can then be taken to mitigate (potential) adverse effects.

In addition, to the patient themselves, the role of family members in monitoring safe practice, can be equally important. In settings where patients are especially vulnerable and unable to look after themselves (e.g. paediatrics and care of the elderly) families are often the patients primary source of strength and support, thus their role in ensuring safety takes on a particularly important role. Despite the important contributions that family members could make, it is currently not clear what their attitudes towards involvement would be and/or their willingness to voice any safety-related concerns. However, drawing from the wider literature on patients themselves, evidence strongly suggests patients find it harder to ask questions that could be perceived as challenging the clinical abilities of HCPs (e.g. *'have you washed your hands?'*) than those related to more general aspects of their recovery (*'how long will I be in hospital for?'*)^{6,11,13-17}. Fear of reprisal, being uncomfortable/anxious about asking, undermining HCPs' clinical abilities and adversely affecting the HCP-patient relationship are key reasons for patients' reluctance to participate¹⁸⁻²¹. To improve participatory levels research has shown that by HCPs giving patients encouragement to 'speak-up' about safety-related issues a significant positive impact on their willingness to be involved can be observed^{11,13,14,22}. It is likely (but yet to be empirically explored) that HCP encouragement could pose analogous effects on family members' willingness to ask safety-related questions. To date however, the extent to which HCPs would support such questioning from patient's families is unknown. Gaining this understanding could be critical to the successful engagement of families in promoting safety and could help to explain why HCPs may support such involvement in some situations but not others.

In previous research we conducted in Switzerland and the UK we used vignettes to explore HCPs' attitudes towards patient involvement in two different error scenarios: poor hand hygiene of the HCP and incorrect medication for the patient^{23,24}. We found that several factors influenced HCPs' level of support for being questioned by patients. Most notably, HCPs viewed patient involvement more favourably if the error described in the scenario actually occurred (i.e. the HCP had not cleaned their

1
2
3 hands before treating the patient), if the patient posed the question in a polite vs. challenging way and
4 if the HCP responded in a helpful and reassuring manner (i.e. the HCP apologised and cleaned their
5 hands). In the present paper we aim to build on our previous research and to address the apparent gap
6 in the evidence-base by examining HCPs' attitudes towards family involvement in safety. Our specific
7 research question was: what are the predictors of doctors' and nurses' attitudes towards family
8 members questioning HCPs: 1) about the HCPs' HH, and; 2) about the patient's medication?
9
10
11

12 **Methods**

13 **Design**

14
15
16 A cross-sectional factorial survey containing vignettes was employed. The survey is an adaption of a
17 survey previously developed and applied by the authors²³⁻²⁵. In total 8 different surveys were used,
18 each of which comprised vignettes on two types of potential errors; a possible medication error and
19 potentially missed hand disinfection. Each vignette consisted of 7 dichotomous variables (factors)
20 each with two levels that were chosen in accordance with previous research and apriori hypotheses²³⁻
21 ²⁵. Three factors in the vignettes related to the family member (relation to the patient (e.g. parent,
22 child), sex, and the way in which they questioned the HCP in the scenario), two related to the HCP
23 (occupation and reaction to the family member's question), and two were error-related (correct/false
24 attribution of error and if the error was witnessed by another HCP). The seven variables generated 128
25 possible combinations. Using experimental design software this was reduced to 8 combinations of
26 random pairings of the two clinical scenarios in a fractional main effects design²⁶ (see Box 1 for
27 examples of vignettes).
28
29
30
31
32
33
34
35
36

37
38 Box 1 here
39

40 **Measures**

41
42
43 A 22-item survey was developed to assess HCPs' attitudes towards family involvement in two
44 different error scenarios, one relating to the hand hygiene of the HCP and the other relating to the
45 patient's medication (11 items on each). Eight items (4 on each error scenario) assessed HCPs' level
46 of agreement with 4 attitudinal statements about the scenario: 1) I approve of the family member's
47 behaviour; 2) the HCP responded in the right manner; 3) the situation would have predominantly
48 positive effects on the family member-HCP relationship, and; 4) I would as a HCP support the family
49 member in asking me about my hand hygiene/the patient's medication. A 7-point Likert response
50 scale was used ranging from 'strongly disagree' to 'strongly agree' (higher scores indicating more
51 favourable responses).
52
53
54
55
56
57
58
59
60

1
2
3 Fourteen items (7 on each scenario) explored HCPs 'affective' ratings of the family member
4 intervening (i.e. how they would feel if they were in the situation described in the scenario and were
5 questioned by a patient's family member). HCPs were asked: '*If you were the HCP, how would the*
6 *described situation be for you?*'. Responses were presented as 7 semantic differentials: 1) bad – good;
7
8 2) difficult – easy; 3) confrontational – not confrontational at all; 4) uncomfortable – comfortable; 5)
9 not helpful at all – very helpful; 6) very embarrassing – not embarrassing at all; 7) very challenging –
10 not challenging at all. A 7-point response scale was used with the semantic differentials serving as
11 anchor labels (higher scores indicating more favourable responses).
12
13
14
15

16 Prior to data collection the survey was tested on 20 HCPs (12 doctors and 8 nurses) and minor
17 iterations were made to ensure face validity and comprehension of survey items.
18
19

20 **Participants**

21
22
23 Data were collected from doctors and nurses from general medical and surgical wards at five hospitals
24 in London (N=3), Leicester (N=1) and York (N=1) between October 2013-March 2014. HCPs were
25 purposively sampled and approached face-face on the hospital wards, provided with an explanation of
26 the study and asked for their consent to participate. The study was considered by the Chair of
27 Hampstead's National Research Ethics Committee and classified as exempt from review.
28
29
30

31 **Data analysis**

32
33
34 Data were analysed using STATA Version 13. Mean scores for survey items were compared
35 according to the error scenario and vignettes attributes. Significant differences were analysed using T
36 tests. Scale reliability was computed (Cronbachs Alpha) for the affective rating items for each error
37 scenario (N=7) and the mean scale score was calculated. Multiple regression analyses were performed
38 to examine the effect of vignette attributes and participants' characteristics (entered as predictor
39 variables) on attitudes towards family member's involvement. Sample size was calculated based on
40 recommendations for the use of regression analysis in behavioural research^{27,28}. Five regression
41 models were conducted for each error scenario (10 in total) relating to each of our key outcome
42 measures: 1) approval of family member's behaviour; 2) approval of HCPs response to the family
43 member; 3) support for being asked as a HCP; 4) positive effects on the family member-HCP
44 relationship, and; 5) the overall mean affective rating score. Chow-tests were performed to test if the
45 coefficients in the regression models for the medication error and hand hygiene scenarios were
46 significantly different or whether the models could be pooled. Data were screened for
47 multicollinearity and to ensure parametric assumptions were met. All tests were two-sided. We
48 considered $p < 0.05$ to be significant.
49
50
51
52
53
54
55
56
57
58
59
60

Results

Participant characteristics

In total, 209 HCPs were approached and 160 HCP completed the survey (77% response rate). 73 (46%) were doctors, and 87 (54%) were nurses, aged between 21-65 years (mean = 37 years; SD = 10.4). 102 (64%) responders were female. Participants had on average 11 years of professional experience (SD = 10 years). HCPs that declined participation did so because they said they were too busy (N=40) or did not want to take part in the study (N=9).

Findings in relation to error frame

Across all scenarios, HCPs were supportive of the family member intervening (i.e. questioning the HCP) (mean approval score=5.8, CI 5.6-5.9). However, only 41% agreed that such behaviour would have positive effects on the family member-HCP relationship (responders with ratings >4). There were no significant differences in HCPs' responses to family members intervening in the medication error frame compared to the hand hygiene frame (Table 1).

Table 1 here

Affecting ratings scores

There was high internal consistency between HCPs' affective ratings scores (Cronbachs Alpha = 0.90). Thus composite scores were calculated (i.e. overall mean score of the seven affective ratings per person). There were no significant differences in the affective ratings or in the composite score in the medication error frame versus the hand hygiene frame. Doctors provided systematically more positive affective ratings as compared to nurses (Table 2).

Table 2 here

Correlations between affective rating scores and key outcome measures

HCPs' mean affective rating scores (composite measure) and responses to the 4 attitudinal judgments were only weakly correlated: I approve of the family members behaviour ($r= 0.08$, $p=0.18$); support for being asked as a HCP ($r= 0.10$, $p=0.07$); the HCP responded in the correct manner ($r= 0.12$, $p=0.03$); the situation would have positive effects on the family member-HCP relationship ($r = 0.26$, $p<0.001$). Thus, overall, HCPs were more likely to expect positive effects on the family member-HCP relationship if they also perceived the HCP behaviour more favourably.

Results of the regression analyses

In multiple regression analyses, the impact of vignette attributes and respondents' characteristics on each of the survey questions were modelled. The results of the Chow tests revealed that the coefficients of the medication error and the hand hygiene models were not equal for three out of five outcomes measures (approval of behaviour; support of being asked as a HCP; affective rating composite score). Based on these findings we estimated separate models for the different error frames. The results of the regression analyses are displayed in Tables 3-5.

Tables 3-5 here

The single most important predictor variable in all models was the described HCP response to the family member intervening (variable nr 7 in the tables). A discouraging HCP response (as compared to an encouraging response) was associated with decreased approval and support of family member's behaviour and affective ratings and had strong negative impact on the anticipated HCP-family member relationship. In both error frames, HCP reactions to the family member's behaviour were strongly associated with respondents' evaluations of whether the HCP responded in the right manner - a discouraging reaction was clearly judged negatively by participants.

The hypothetical family member's sex (variable nr 1) played a role in the evaluation of the interactions with staff (HCP response to being questioned and effects on the HCP-family member relationship) with male family members' interventions viewed less positively by responders. Family member's sex contributed considerably to HCP's affective ratings but with opposite directions in the medication and hand hygiene frames. Irrespective of vignette attributes, affective ratings were more positive when the family member intervening was a male in the hand hygiene frame while they were higher for female family members in the medication error scenario.

Whether the family member intervening was a daughter/son of a senior patient or mother/father of a hospitalized child (variable nr 2) was only marginally and sporadically associated with the outcome measures.

When family members were described as intervening in a challenging rather than an inquiring way (variable nr 5) this only had negative effects on approval and support of the behaviour in the medication error frames. In particular, it did not influence the affective ratings.

The profession of the HCP involved in the interaction with the family member (variable nr 4) impacted on the evaluations of the medication errors frames: The behaviour was more likely to be

1
2
3 approved and seen as positively affecting the relationship in scenarios in which the family member
4 intervened towards a doctor rather than a nurse.
5
6

7 The attribution of error (variable nr 6) was an important predictor in the hand hygiene models in
8 particular. A false attribution of missed hand hygiene decreased approval and support of the behaviour
9 and also had negative associations with the anticipated HCP-family member relationship. Notably, a
10 false attribution of error had positive effects on the affective ratings in the medication error frame.
11
12

13
14 Whether the situation was witnessed by another HCP (variable nr 3) was only significantly associated
15 with the affective ratings of the medication error frame but not with any of the other outcomes. The
16 family member's behaviour was perceived less positive when the situation was witnessed by co-
17 workers.
18
19

20
21 In comparison to vignette attributes, personal characteristics of respondents (variables 8-11) had only
22 minor effects on their judgments: nurses as compared to doctors (variable nr 8) were significantly
23 more likely to approve of the family member's behaviour (in the hand hygiene scenarios) and support
24 the family member (both error frames). However, even after adjusting for vignette characteristics,
25 doctors were more likely to provide higher affective ratings as compared to nurses. Other
26 respondent's characteristics had only unsystematic and marginal effects on vignette ratings.
27
28
29
30

31 **Discussion**

32
33 This experimental vignette study set out to explore factors that influence HCPs' attitudes towards
34 family member's involvement in two safety-relevant areas; asking HCPs about their hand hygiene and
35 checking patients' medication. To our knowledge, this is the first study into the acceptance of family
36 members involvement in this area. Overall, we found a high level of support and approval for families
37 intervening among surveyed HCPs in both error scenarios. However, over all described situations
38 60% disagreed that the family member's behaviour would have positive effects on the relationship
39 with the HCP. Across vignette attribute specifications, no differences between respondents' attitudes
40 towards the hand hygiene and the medication error frames were observed. Two factors in particular
41 appeared to have a strong effect on attitudes – correct attribution of the error and how the HCP
42 reacted to the family member's involvement. Doctors (vs. nurses) provided systematically more
43 positive affective ratings to the vignettes. In particular, they rated the hypothetical situations as easier
44 and more comfortable to manage and as less embarrassing.
45
46
47
48
49
50
51
52

53
54 We found some important differences to our previous studies on HCPs' acceptance of patient
55 involvement in safety^{23,24}. First, respondents' evaluations of the vignettes were only slightly and
56 unsystematically affected by how the family member intervened (challenging vs. inquiring).
57
58
59
60

1
2
3 Conversely however, our previous research revealed that patient behaviour was a strong predictor of
4 HCPs' approval; a finding also reflected in the wider literature. Garcia-Williams reported that HCPs
5 level of support in patients asking them about their hand hygiene would 'depend' on how they were
6 asked¹⁵. Second, HCPs in previous studies were much more positive about patient engagement in
7 medication safety and were more reluctant about involvement in hand hygiene. In this study, we
8 found some differences in attributes affecting outcomes measures (e.g., approval and affective
9 ratings), but only minor differences in overall level of support between medication error and hand
10 hygiene frames. Taken together, these results could potentially suggest that HCPs actually view
11 family involvement differently as it involves a different dynamic to the patient interacting with them.
12 Family engagement in safety seems to trigger less emotionally and strong responses by HCPs. The
13 fact that the affective ratings were not as strong as in our previous studies also lends some support to
14 this hypothesis.
15
16
17
18
19
20
21

22 Another apparent difference between this study and prior research into HCP attitudes is that doctors in
23 our study provided more favourable affective ratings than nurses. In previous research, including
24 those using similar vignettes, nurses were not only more willing to support being questioned
25 themselves about safety-related issues by patients^{23,24,29}, they also reported more positive affective
26 ratings^{23,24}. We can only speculate on the reasons for this finding. One explanation may be that
27 doctors less often experience situations in which family members question or challenge them. As a
28 consequence, they may underestimate the difficulty of the situation and emotionally demanding
29 interaction.
30
31
32
33
34
35

36 This study is the first of its kind to provide insight into HCPs' acceptance of family members
37 questioning them about hand hygiene and medication safety-related concerns. A main strength is that
38 we used an experimental design to systematically manipulate factors and observe the effects of this
39 manipulation, something we would not be able to control for in observational studies. Still, direct
40 observation studies of family-HCP interactions relating to patient safety are warranted. This would
41 deepen our understanding of how, where, and by whom such interactions are initiated and how
42 satisfactory they are for HCP and family members. A second strength is that we can directly explore
43 areas of agreement and differences between HCPs' attitudes towards patients' and family members'
44 involvement in patient safety as we used the same factors and frames as in our previous studies.
45 Finally, the response rate to the survey is reasonably good, in particular for a HCP sample.
46
47
48
49
50
51

52 The main limitation of our study is that we assessed attitudes and this is not always reflective of
53 behaviour. We thus do not know how participants in our study would in reality respond to families
54 engaging in the safety of their loved ones. We used "true life" vignettes to improve and assimilate
55 respondents' conceptions of family behaviour but the responses are still biased by "hypotheticality".
56
57
58
59
60

1
2
3 The sample is relatively small and the wider generalisability of our results needs to be assessed in
4 future studies. We also do not know whether any patient involvement activities in the hospitals may
5 have affected the results. Due to design and sample size reasons, we could not model interactions of
6 vignette attributes though these may be important for judgments about the scenarios. Finally, it is
7 worth noting that this was a cross-sectional study, therefore we cannot make causal inferences about
8 the relationships between variables.
9
10
11

12
13 This study serves only as an initial step into research in family engagement in safety. Today, very
14 little is known about family members attitudes and feelings about engagement, let alone strategies to
15 encourage involvement and whether families would be more willing to act on their loved ones behalf
16 than if they themselves were a patient in hospital. Future research is needed to enlighten the reasons
17 and motivations underlying the attitudes as expressed by HCPs in our study. The vignettes could serve
18 as a starting point in qualitative interview studies or focus groups with HCPs. Studies could use a
19 similar design to explore family members' attitudes towards involvement - this would be an
20 interesting parallel and is yet to be explored. It would be valuable to examine patients' perspectives on
21 their families intervening. There may be occasions where patients do not want their family members
22 to question staff. We also suggest studying the safety-related interactions between HCPs and family
23 members in other medical settings, or even in comparison between settings, to gain a deeper
24 understanding of the relevance of context. For example, family members of intensive care patients
25 and the roles attributed to them may be viewed differently to other care settings due to patients often
26 being unable to act for themselves in this context. HCPs in intensive care are also more used to being
27 questioned and challenged by family members and may therefore experience less emotional distress
28 when confronted by family members about safety-related issues. Also, little is known about the
29 benefits and adverse effects of family involvement. While family members questioning HCPs could
30 result in positive effects (i.e. improved safety), the potential adverse consequences of involving them
31 remain unknown, e.g. it could potentially heighten anxiety, placing inappropriate responsibility on
32 them when they are already worried about their loved, or it could make them fear if they do not
33 question HCPs the patient will be at increased risk. It may also create tensions in their relationship
34 with HCPs - though our results do not seem to indicate this.
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8 **Acknowledgements:** We thank the research participants for their time in completing our survey.
9

10
11 **Contributorship statement:** DS conceptualised the study and designed the survey instrument with
12 the assistance of RD. RD monitored data collection and entry for the survey and DS analysed data.
13 Both RD and DS drafted and revised the paper. RD is guarantor and affirms this is an honest and
14 transparent account of the study being reported; that no important aspects of the study have been
15 omitted, and that; any discrepancies from the study have been explained. MS, RS and SS collected the
16 data and provided feedback on the paper. All authors had full access to all of the data (including
17 statistical reports and tables) in the study and can take responsibility for the integrity of the data and
18 the accuracy of the data analysis.
19
20
21
22
23

24
25 **Competing interests:** *"All authors have completed the Unified Competing Interest form at*
26 *www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author Rachel Davis)*
27 *and declare that (1) RD, MS, RS, SS, and DS have support from Imperial College London for the*
28 *submitted work; (2) have no relationships with companies that might have an interest in the submitted*
29 *work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships*
30 *that may be relevant to the submitted work and; (4) have no non-financial interests that may be*
31 *relevant to the submitted work"*
32
33
34
35
36

37 **Funding:** The Clinical Safety Research Unit is affiliated with the Centre for Patient Safety and
38 Service Quality at Imperial College Healthcare NHS Trust which is funded by the National Institute
39 of Health Research. The opinions expressed are those of the authors and do not necessarily reflect the
40 policies or views of the National Institute of Health Research. The NIHR played no role in the study
41 design; collection, analysis, and interpretation of data; writing of the manuscript; or the decision to
42 submit the article for publication. Researchers were independent of influence from the NIHR.
43
44
45
46
47

48 **Data sharing:** Informed consent to participate in the study was gained from all research participants.
49 The data presented in this manuscript are anonymised thus there is no risk of participant
50 identification. No additional data available.
51
52
53

54 **Ethical approval:** The study was considered by the Chair of Hampstead's National Research Ethics
55 Committee and classified as exempt from review.
56
57
58
59
60

References

1. World Health Organisation (WHO). Quality of Care: Patient Safety. Fifty-fifth World Health Assembly, 2002. <http://www.who.int/patientsafety/worldalliance/ea5513.pdf?ua=1>
2. WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge Clean Care is Safer care, 2009
http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf?ua=1
3. WHO. Global priorities for research in patient safety (first edition). The Research Priority Setting Working Group, 2008.
http://www.who.int/patientsafety/research/priorities/global_priorities_patient_safety_research.pdf
4. Vincent C, Coulter A. Patient safety: what about the patient? *Quality and Safety in Healthcare*, 2002; 11: 76-80.
5. Coulter A, Ellins J. Patient-focused interventions: A review of the evidence. Chapter 4 'Improving patient safety', pgs 143-178. Health Foundation, 2006.
6. Schwappach D. Engaging patients as vigilant partners in safety. A systematic review. *Medical Care Research and Review*, 2010; 67:2: 119-148
7. Lawton R, Armitage G. The role of the patient in clinical safety. Health Foundation, 2012.
8. WHO. Exploring patient participation in reducing healthcare-related safety risks. WHO, 2013
http://www.euro.who.int/_data/assets/pdf_file/0010/185779/e96814.pdf
9. Davis R, Sevdalis N, Jacklin R, et al. An examination of opportunities for the active patient in improving patient safety. *Journal of Patient Safety*, 2012; 8:1:36-43.
10. Davis R, Vincent C, Murphy M. Blood transfusion safety: The potential role of the patient. *Transfusion Medicine Reviews*, 2011; 25:1:12-23.
11. Davis R, Sevdalis N, Vincent C. Patient involvement in patient safety- How willing are patients to participate? *BMJ Quality and Safety*, 2011; 20:108-114.
12. Unruh KT, Pratt W. Patients as actors: the patient's role in detecting, preventing, and recovering from medical errors. *International Journal of Medical Informatics* 2007; 76(Suppl 1):S236-44.
13. Davis R, Koutantji M, Vincent C. How willing are patients to question healthcare staff on issues related to the quality and safety of their healthcare? An exploratory study, *Quality and Safety in Health Care*, 2008. 17; 90-96.

- 1
- 2
- 3 14. Longtin, Y et al. 2009. Patients' beliefs and perceptions of their participation to increase
- 4 healthcare worker compliance with hand hygiene. *Infection Control and Hospital*
- 5 *Epidemiology*, 2009; 30:9: 830-839.
- 6
- 7 15. Garcia-Williams A, Brinsley-Rainisch K, Schille S, et al. To ask or not to ask? The results of
- 8 a formative assessment of a video empowering patients to ask their health care providers to
- 9 perform hand hygiene. *Journal of Patient Safety*, 2010; 6:2: 80-85.
- 10
- 11 16. Hibbard J, Peters E, Slovic P, et al. 2005. Can patients be part of the solution? Views on their
- 12 role in preventing medical errors. *Medical Care Research and Review* 2005; 62: 601-616.
- 13
- 14 17. Marella, W. M. et al. (2007). Healthcare consumers' inclination to engage in selected patient
- 15 safety practices: a survey of adults in Pennsylvania. *Journal of Patient safety*, 3, 184-189.
- 16
- 17 18. Pittet D, Panesar SS, Wilson K, et al. Involving the patient to ask about hospital hand
- 18 hygiene: a National Patient Safety Agency feasibility study *Journal of Hospital Infection*
- 19 2011; 77: 299-303.
- 20
- 21 19. Ottum A, Sethi AK, Jacobs EA, et al. Do patients feel comfortable asking healthcare workers
- 22 to wash their hands? *Infection Control and Hospital Epidemiology*, 2012; 33:12:1282-1284
- 23
- 24 20. Michealson K, Sanders JL, Zimmer SM, et al. Overcoming patient barriers to discussing
- 25 physician hand hygiene: do patients prefer electronic reminders to other methods? *Infection*
- 26 *Control and Hospital Epidemiology*, 2013; 34:9:929-934.
- 27
- 28 21. Julian K, Subramanian K, Brumbach A, et al. Attitudes of healthcare workers and patients
- 29 towards individualised hand hygiene reminders. *Infection Control and Hospital*
- 30 *Epidemiology*, 2008; 29:8:781-782.
- 31
- 32 22. WHO Alliance for Patient Safety Hand Hygiene Survey Results from Phase One October
- 33 2007 http://www.who.int/patientsafety/hand_hygiene_survey.pdf
- 34
- 35 23. Davis R, Briggs M, Arora S, Schwappach D. Predictors of healthcare professionals' attitudes
- 36 towards involvement in safety-related behaviours. *Journal of Evaluation and Clinical Practice*,
- 37 2014; 20:1:12-9.
- 38
- 39 24. Schwappach D, Davis R, Frank O. A vignette study to examine healthcare professionals'
- 40 attitudes toward patient involvement in error prevention. *Journal of Evaluation and Clinical*
- 41 *Practice*, 2013;19:5:840-8
- 42
- 43 25. Schwappach DL, Hochreutener MA, Wernli M. Oncology nurses' perceptions about involving
- 44 patients in the prevention of chemotherapy administration errors. *Oncol Nurs Forum* 2010;
- 45 37:2:E84-E91.
- 46
- 47 26. Bradley M. Users manual for SPEED. version 2.1 stated preference editor and designer. The
- 48 Hague: Hague Consulting Group; 1991.
- 49
- 50 27. Park C, Dudycha A. A cross-validation approach to sample size determination. *Journal of the*
- 51 *American Statistical Association*, 1974; 69: 214-218.
- 52
- 53 28. Pedhazur EJ. Multiple regression in behavioral research. Harcourt Brace: Orlando, FL, 1997.
- 54
- 55
- 56
- 57
- 58
- 59
- 60

- 1
2
3 29. Davis RE, Sevdalis N, Vincent CA. Patient involvement in patient safety: the health-care
4 professional's perspective. Journal of Patient Safety, 2012;8:4:182-8
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

Tables and boxes

Box 1: Example vignettes

Factor	Levels with coding
A Family member's sex	0: Female 1: Male
B Relation to patient	0: Parent to patient 1: Child of patient
C Situation witnessed	0: No, patient and HCP are alone 1: Yes, event is witnessed by other HPC
D Staff occupation	0: Nurse 1: Doctor
E Patient's behaviour	0: Inquiring 1: Challenging
F Attribution of error	0: True, HCP did make an error 1: False, HCP did not make an error
G Staff response	0: Encouraging 1: Discouraging

Error scenario 1, vignette A₀B₀C₁D₁E₀F₀G₁

Mrs Smith is mother to a five year old boy. Mrs Smith's son has been in hospital for a few days. He had a complicated appendectomy. Mrs Smith is present at hospital daily to watch after her son. During the morning several doctors and nurses enter the room. A doctor inspects the wound dressing of Mrs Smith's son. Mrs Smith looks anxious and asks: *excuse me, shouldn't you need to wash your hands?* As it is a very busy morning the doctor had in fact forgot to wash his hands. The doctor rolls his eyes and disinfects his hands using alcohol gel.

Error scenario 2, vignette A₁B₀C₀D₁E₁F₀G₀

Mr Brown is father to a five year old boy. Mr Brown's son has been in hospital for a number of days. He is suffering from severe heart problems. Mr Brown is present at hospital daily to watch after his son. His son has been prescribed several drugs. Early this morning, the nurse gave the medication to Mr Brown and instructed him that his son should take them with breakfast. Later on in the morning a doctor enters the room. The doctor asks Mr Brown's son how he is doing. Mr Brown looks angry and states: *Can you please check these red tablets. I do not think these are meant to be for my son!* The doctor had been very busy when writing prescriptions yesterday and had been interrupted several times. The doctor checks the medication against the chart and says: *'oh yes it is very good that you ask. I am really sorry it seems that your son indeed has been given the wrong medication. Your prescription should not have changed.*

Note: letters in Box 1 indicate factors and numbers in subscripts represent the levels

Table 1. Results in relation to error frame (N=160)

Outcome measure (survey questions)	Error scenario*		p
	Hand hygiene Mean, [CI]	Medication error Mean, [CI]	
I approve of the family member's behaviour	5.9 [5.6,6.1]	5.7 [5.4,5.9]	0.2589
The HCP responded in the right manner	4.8 [4.5,5.2]	4.7 [4.3,5.0]	0.5015
The situation would have predominantly positive effects on the caregiver-HCP relationship	4.0 [3.7,4.4]	3.8 [3.5,4.2]	0.3852
I would as a HCP support the caregiver asking me	6.0 [5.8,6.2]	6.0 [5.8,6.2]	0.9650

**Level of agreement was measured on a 7-point Likert response scale with higher numbers indicating higher levels of agreement.*

Table 2. Results of affective ratings scores (N=160)

Affective items	Mean rating* [CI]			p
	Total	Doctors	Nurses	
Bad-Good	3.6 [3.4,3.8]	4.0 [3.7,4.2]	3.4 [3.1,3.7]	0.0041
Difficult-Easy	3.7 [3.5,3.9]	4.1 [3.8,4.3]	3.3 [3.1,3.6]	0.0001
Confrontational -Not confrontational	3.9 [3.7,4.1]	4.2 [3.9,4.5]	3.7 [3.4,4.0]	0.0243
Not helpful - Very helpful	4.7 [4.6,4.9]	4.8 [4.6,5.0]	4.7 [4.4,4.9]	0.4661
Very embarrassing-Not embarrassing	3.8 [3.5,4.0]	4.3 [4.0,4.6]	3.3 [3.0,3.6]	<0.0001
Challenging -Not challenging	4.1 [3.9,4.3]	4.4 [4.1,4.7]	3.8 [3.5,4.1]	0.0040
Very uncomfortable-Comfortable	3.6 [3.4,3.8]	4.1 [3.8,4.3]	3.2 [2.9,3.5]	<0.0001
Composite, affective score**	3.9 [3.8,4.1]	4.2 [4.0,4.5]	3.6 [3.4,3.8]	0.0001

*A 7-point response scale was used with the semantic differentials serving as anchor labels (higher scores indicating more favourable responses)
 ** Mean over the seven ratings per person

Table 3. Results of multiple regression analyses (N=160)

Variable nr	Vignette attributes	Approval of family member's behaviour						The HCP responded in the right manner					
		HH Error Vignettes			Medication Error vignettes			HH Error Vignettes			Medication Error vignettes		
		Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p
1	Family member gender (1=male)	0.047	-0.383,0.477	0.830	-0.042	-0.422,0.337	0.825	-0.779	-1.321,-0.236	0.005	-0.403	-0.881,0.075	0.098
2	Relation to patient (1=daughter/son of patient)	-0.251	-0.679,0.177	0.249	-0.436	-0.813,-0.058	0.024	0.232	-0.308,0.772	0.398	0.015	-0.462,0.491	0.952
3	Situation witnessed (1=yes)	0.056	-0.385,0.496	0.803	-0.319	-0.692,0.053	0.092	-0.072	-0.627,0.483	0.799	0.299	-0.171,0.769	0.210
4	Staff occupation (1=doc)	0.110	-0.316,0.535	0.611	0.429	0.037,0.820	0.032	0.226	-0.310,0.763	0.406	0.621	0.126,1.115	0.014
5	Family member behaviour (1=challenging)	-0.384	-0.808,0.040	0.076	-1.362	-1.737,-0.987	0.000	0.386	-0.149,0.920	0.156	-0.210	-0.683,0.263	0.382
6	Attribution of error (1=false)	-1.033	-1.471,-0.594	0.000	-0.683	-1.059,-0.306	0.000	-0.779	-1.331,-0.226	0.006	-0.422	-0.897,0.053	0.081
7	Staff response (1=discouraging)	-0.583	-1.013,-0.153	0.008	-0.756	-1.143,-0.370	0.000	-2.799	-3.341,-2.257	0.000	-3.119	-3.606,-2.632	0.000
	Respondents' characteristics												
8	Doctor or nurse (1=nurse)	0.520	0.040,1.000	0.034	0.083	-0.340,0.506	0.699	0.498	-0.107,1.103	0.106	0.355	-0.179,0.889	0.191
9	Age, years	0.008	-0.038,0.054	0.726	-0.034	-0.075,0.006	0.097	-0.024	-0.082,0.034	0.410	0.010	-0.041,0.062	0.686
10	Sex (1=female)	0.019	-0.488,0.525	0.942	-0.092	-0.539,0.355	0.686	-0.731	-1.370,-0.092	0.025	-0.343	-0.907,0.220	0.231
11	Years of experience, years	-0.016	-0.065,0.034	0.534	0.048	0.005,0.092	0.030	0.011	-0.052,0.073	0.739	-0.033	-0.088,0.022	0.237
12	constant	6.449	4.875,8.022	0.000	8.010	6.741,9.278	0.000	7.596	5.612,9.580	0.000	6.261	4.661,7.861	0.000
	R-sqr	0.229			0.400			0.467			0.581		
	overall model p	<0.001			<0.001			<0.001			<0.001		

Table 4. Results of multiple regression analyses (N=160)

Variable nr	Vignette attributes	Positive effects on the family member/HCP relationship						Support for being asked as a HCP					
		HH Error Vignettes			Medication Error vignettes			HH Error Vignettes			Medication Error vignettes		
		Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p	Coeff	95%CI	p
1	Family member gender (1=male)	-0.523	-1.072,0.026	0.062	-0.596	-1.073,-0.120	0.015	-0.308	-0.676,0.060	0.101	-0.120	-0.508,0.267	0.540
2	Relation to patient (1=daughter/son of patient)	0.321	-0.226,0.867	0.248	0.038	-0.437,0.512	0.875	0.389	0.023,0.756	0.038	-0.195	-0.581,0.191	0.320
3	Situation witnessed (1=yes)	0.045	-0.517,0.607	0.874	0.132	-0.336,0.600	0.577	0.293	-0.084,0.669	0.127	-0.186	-0.566,0.195	0.336
4	Staff occupation (1=doc)	0.050	-0.493,0.593	0.856	0.760	0.267,1.252	0.003	0.395	0.031,0.759	0.034	0.072	-0.329,0.472	0.724
5	Family member behaviour (1=challenging)	-0.127	-0.668,0.413	0.642	-0.454	-0.926,0.017	0.059	0.225	-0.138,0.587	0.223	-0.432	-0.815,-0.048	0.028
6	Attribution of error (1=false)	-0.943	-1.502,-0.384	0.001	0.098	-0.375,0.571	0.683	-0.725	-1.100,-0.350	0.000	0.162	-0.223,0.547	0.408
7	Staff response (1=discouraging)	-2.245	-2.794,-1.697	0.000	-2.420	-2.905,-1.934	0.000	-0.509	-0.877,-0.141	0.007	-0.379	-0.774,0.016	0.060
	Respondents' characteristics												
8	Doctor or nurse (1=nurse)	0.400	-0.212,1.012	0.199	0.172	-0.360,0.703	0.524	0.490	0.079,0.900	0.020	0.580	0.148,1.013	0.009
9	Age, years	-0.004	-0.063,0.055	0.897	-0.003	-0.054,0.048	0.915	-0.007	-0.047,0.032	0.711	0.005	-0.037,0.046	0.821
10	Sex (1=female)	-0.377	-1.024,0.269	0.251	-0.135	-0.696,0.427	0.636	-0.139	-0.573,0.294	0.527	-0.153	-0.610,0.303	0.508
11	Years of experience, years	-0.011	-0.074,0.052	0.733	-0.019	-0.074,0.035	0.488	-0.005	-0.048,0.037	0.802	0.003	-0.041,0.048	0.893
12	constant	6.043	4.035,8.051	0.000	5.374	3.780,6.968	0.000	6.297	4.950,7.644	0.000	6.135	4.839,7.431	0.000
	R-sqr	0.377			0.484			0.255			0.124		
	overall model p	<0.001			<0.001			<0.001			0.042		

Table 5. Results of multiple regression analyses (N=160)

		Affective ratings scores					
		Hand hygiene vignettes			Medication error vignettes		
		Coeff	95% CI	p	Coeff	95% CI	p
Variable nr	Vignette attributes						
1	Family member gender (1=male)	0.786	0.414,1.159	0.000	-0.846	-1.198,-0.493	0.000
2	Relation to patient (1=daughter/son of patient)	0.015	-0.356,0.386	0.935	0.415	0.064,0.767	0.021
3	Situation witnessed (1=yes)	0.179	-0.203,0.560	0.356	-0.369	-0.715,-0.022	0.037
4	Staff occupation (1=doc)	-0.048	-0.417,0.321	0.797	0.170	-0.195,0.534	0.359
5	Family member behaviour (1=challenging)	0.108	-0.260,0.475	0.564	-0.158	-0.506,0.191	0.374
6	Attribution of error (1=false)	-0.336	-0.716,0.044	0.083	1.288	0.938,1.638	0.000
7	Staff response (1=discouraging)	-1.062	-1.435,-0.690	0.000	-0.592	-0.952,-0.233	0.001
Respondents' characteristics							
8	Doctor or nurse (1=nurse)	-0.525	-0.941,-0.109	0.014	-0.359	-0.753,0.034	0.073
9	Age, years	0.025	-0.015,0.065	0.226	0.017	-0.021,0.055	0.378
10	Sex (1=female)	-0.113	-0.552,0.327	0.613	-0.327	-0.743,0.089	0.122
11	Years of experience, years	-0.019	-0.062,0.024	0.375	-0.012	-0.052,0.029	0.572
12	constant	3.772	2.408,5.136	0.000	3.824	2.644,5.005	0.000
	R-sqr	0.320			0.439		
	overall model p	<0.001			<0.001		

1
2
3 Predictors of healthcare professionals' attitudes towards family involvement in safety-relevant
4 behaviours: A cross-sectional factorial survey study~~Predictors of healthcare professionals'~~
5 ~~attitudes towards family involvement in safety-relevant behaviours~~
6
7
8

9
10 **Authors and affiliations**

11 Davis R¹, Savvopoulou M¹, Shergill R², Shergill S³, Schwappach, D^{4,5}.

12
13
14 ¹ Centre for Patient Safety and Service Quality, Division of Surgery, 5th Floor Medical School
15 Building, Imperial College London, St Mary's Campus, Norfolk Place, London, W2 1PG.

16 ² Leicester Medical School, University Road, Leicester, LE1 9HN

17 ³ York Medical School, University of York, North Yorkshire YO10 5DD

18 ⁴ Swiss Patient Safety Foundation. Asylstr. 77. 8032 Zurich, Switzerland.

19 ⁵ Institute of Social and Preventive Medicine (ISPM). University of Bern. Switzerland
20
21
22
23
24

25 Correspondence to: Rachel Davis. email: rachel.davis@imperial.ac.uk
26
27
28
29
30
31
32

33 **Word count:** 29853351
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Abstract

Objectives~~Background:~~ To investigate predictors of healthcare professionals (HCPs) attitudes towards family involvement in safety-relevant behaviours. Patients' families can play an important role in promoting their safety during their stay in hospital. Healthcare professionals (HCPs) could help to increase family involvement in their loved one's safety by encouraging them to speak up if they have any safety related concerns. To date however, little is known about factors that determine HCPs' attitudes towards family involvement in this context.

~~**Objective:** To investigate predictors of HCPs' attitudes towards family involvement in safety-relevant behaviours.~~

Design: A cross-sectional fractional factorial survey that assessed HCPs' attitudes towards family involvement in two error scenarios relating to hand hygiene and medication safety. Each survey comprised two randomised vignettes that described the potential error, how the family member communicated with the HCP about the error and how the HCP responded to the family member's question.

Setting: 5 teaching hospitals in London, the and the Midlands and York. HCPs were approached on a range of medical and surgical wards.

Participants: 160 HCPs (73 doctors; 87 nurses) aged between 21-65 years (mean: 37): 102 were female.

Outcome measures: HCP approval of family member's behaviour; HCP reaction to the family member; anticipated effects on the family member-HCP relationship; HCP support for being questioned~~asked~~ about hand hygiene/medication; affective rating responses.

Results: HCPs supported family member's intervening (88%) but only 43.41% agreed~~that~~ this would have positive effects on the family member/HCP relationship. Across vignettes and error scenarios the strongest predictors of attitudes were how the HCP (in the scenario) responded to the family member's~~questioning~~ and whether an error actually occurred. Doctors (vs. nurses) provided systematically more positive affective ratings to the vignettes.

Conclusions: Important predictors of HCPs' attitudes towards family members' involvement in patient safety have been highlighted. In particular, a discouraging response from HCPs decreased support for family members being involved and had strong perceived negative effects on the family-member/HCP relationship.

Strengths and limitations of this study

- This is the first quantitative study to examine factors affecting doctors' and nurses' attitudes towards families questioning them about patient-related safety concerns.
- This paper highlights that the strongest predictors of attitudes were how the HCP (in the scenario) responded to the family member's questioning and whether an error actually occurred.
- We used experimental vignettes to assess important determinants of HCPs' attitudes but the ecological validity of the results remains to be established.
- Doctors and nurses were recruited from several sites across London, the Midlands and Yorkshire but the wider generalizability of the findings needs to be assessed.

Acknowledgements: We thank the research participants for their time in completing our survey.

Contributors: DS conceptualised the study and designed the survey instrument with the assistance of RD. RD monitored data collection and entry for the survey and DS analysed data. Both RD and DS drafted and revised the paper. RD is guarantor and affirms this is an honest and transparent account of the study being reported; that no important aspects of the study have been omitted, and that; any discrepancies from the study have been explained. MS, RS and SS collected the data and provided feedback on the paper. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding: The Clinical Safety Research Unit is affiliated with the Centre for Patient Safety and Service Quality at Imperial College Healthcare NHS Trust which is funded by the National Institute of Health Research. The opinions expressed are those of the authors and do not necessarily reflect the policies or views of the National Institute of Health Research. The NIHR played no role in the study design; collection, analysis, and interpretation of data; writing of the manuscript; or the decision to submit the article for publication. Researchers were independent of influence from the NIHR.

Competing interests: *"All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author Rachel Davis) and declare that (1) RD, MS, RS, SS, and DS have support from Imperial College London for the submitted work; (2) have no relationships with companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work and; (4) have no non-financial interests that may be relevant to the submitted work"*

Ethical approval: The study was considered by the Chair of Hampstead's National Research Ethics Committee and classified as exempt from review.

Data sharing: Informed consent to participate in the study was gained from all research participants. The data presented in this manuscript are anonymised thus there is no risk of participant identification. There is no additional data available.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Competing interests: None.

For peer review only

Introduction

Improving patient safety is an international priority in healthcare¹⁻³. Traditionally efforts to reduce preventable harm have targeted the practices and systems within healthcare organisations and the skills and behaviour of those delivering clinical care. More recently though, the contributions that patients can make to their safety hasve been highlighted^{4,7}, with the last decade in particular seeing a surge of interest in this area^{6,8}. There are numerous opportunities throughout the care pathway for patients to help reduce their risk of healthcare harm^{4,9,10}. Monitoring and questioning the safety practice of healthcare professionals (HCPs) is one area in particular that holds promise¹¹. Patients have been shown to flag up safety problems (e.g. being given the wrong medication) that may otherwise go unnoticed¹² meaning that prompt action can then be taken to mitigate (potential) adverse effects.

In addition, to the patient themselves, the role of family members in monitoring safe practice, can be equally important. In settings where patients are especially vulnerable and unable to look after themselves (e.g. paediatrics and care of the elderly) families are often the patients primary source of strength and support, thus their role in ensuring safety takes on a particularly important role. Despite the important contributions that family members could make, it is currently not clear what their attitudes towards involvement would be and/or their willingness to voice any safety-related concerns. However, drawing from the wider literature on patients themselves, evidence strongly suggests patients find it harder to ask questions that could be perceived as challenging the clinical abilities of HCPs (e.g. *'have you washed your hands?'*) than those related to more general aspects of their recovery (*'how long will I be in hospital for?'*)^{6,11,13-17}. Fear of reprisal, being uncomfortable/anxious about asking, undermining HCPs' clinical abilities and adversely affecting the HCP-patient relationship are key reasons for patients' reluctance to participate¹⁸⁻²¹. To improve participatory levels research has shown that by HCPs giving patients encouragement to 'speak-up' about safety-related issues a significant positive impact on their willingness to be involved can be observed^{11,13,14,22}. It is likely (but yet to be empirically explored) that HCP encouragement could pose analogous effects on family members' willingness to ask safety-related questions. To date however, the extent to which HCPs would support such questioning from patient's families is unknown. Gaining this understanding could be critical to the successful engagement of families in promoting safety and could help to explain why HCPs may support such involvement in some situations but not others.

In previous research we conducted in Switzerland and the UK we used vignettes to explore HCPs' attitudes towards patient involvement in two different error scenarios: poor hand hygiene of the HCP and incorrect medication for the patient^{23,24}. We found that several factors influenced HCPs' level of support for being questioned by patients. Most notably, HCPs viewed patient involvement more favourably if the error described in the scenario actually occurred (i.e. the HCP had not cleaned their

hands before treating the patient), if the patient posed the question in a polite vs. challenging way and if the HCP responded in a helpful and reassuring manner (i.e. the HCP apologised and cleaned their hands). In the present paper we aim to build on our previous research and to address the apparent gap in the evidence-base by examining HCPs' attitudes towards family involvement in safety. Our specific research question was: what are the predictors of doctors' and nurses' attitudes towards family members questioning HCPs: 1) about the HCPs' HH, and; 2) about the patient's medication?

Methods

Design

A cross-sectional factorial survey containing vignettes was employed. The survey is an adaption of a survey previously developed and applied by the authors²³⁻²⁵. In total 8 different surveys were used, each of which comprised vignettes on two types of potential errors; a possible medication error and potentially missed hand disinfection. Each vignette consisted of 7 dichotomous variables (factors) each with two levels that were chosen in accordance with previous research and apriori hypotheses²³⁻²⁵. Three factors in the vignettes related to the family member (relation to the patient (e.g. parent, daughterchild), sex, and the way in which they questioned the HCP in the scenario), two related to the HCP (occupation and reaction to the family member's question), and two were error-related (correct/false attribution of error and if the error was witnessed by another HCP). The seven variables generated 128 possible combinations. Using experimental design software this was reduced to 8 combinations of random pairings of the two clinical scenarios in a fractional main effects design²⁶ (see Box 1 for examples of vignettes).

Box 1 here

Measures

A 22-item survey was developed to assess HCPs' attitudes towards family involvement in two different error scenarios, one relating to the hand hygiene of the HCP and the other relating to the patient's medication (11 items on each). Eight items (4 on each error scenario) assessed HCPs' level of agreement with 4 attitudinal statements about the scenario: 1) I approve of the family member's behaviour; 2) the HCP responded in the right manner; 3) the situation would have predominantly positive effects on the family member-HCP relationship, and; 4) I would as a HCP support the family member in asking me about my hand hygiene/the patient's medication. A 7-point Likert response scale was used ranging from 'strongly disagree' to 'strongly agree' (higher scores indicating more favourable responses).

1
2
3 Fourteen items (7 on each scenario) explored HCPs 'affective' ratings of the family member
4 intervening (i.e. how they would feel if they were in the situation described in the scenario and were
5 questioned by a patient's family member). HCPs were asked: '*If you were the HCP, how would the*
6 *described situation be for you?*'. Responses were presented as 7 semantic differentials: 1) bad – good;
7
8 2) difficult – easy; 3) confrontational – not confrontational at all; 4) uncomfortable – comfortable; 5)
9 not helpful at all – very helpful; 6) very embarrassing – not embarrassing at all; 7) very challenging –
10 not challenging at all. A 7-point response scale was used with the semantic differentials serving as
11 anchor labels (higher scores indicating more favourable responses).
12
13
14

15
16 Prior to data collection the survey was tested on 20 HCPs (12 doctors and 8 nurses) and minor
17 iterations were made to ensure face validity and comprehension of survey items.
18
19

20 Participants

21
22
23 Data were collected from doctors and nurses from general medical and surgical wards at five hospitals
24 in London (N=3), Leicester (N=1) and York (N=1) between October 2013-March 2014. HCPs were
25 purposively sampled and approached face-face on the hospital wards, provided with an explanation of
26 the study and asked for their consent to participate. The study was considered by the Chair of
27 Hampstead's National Research Ethics Committee and classified as exempt from review.
28
29
30
31

32 Data analysis

33
34 Data were analysed using STATA Version 13. Mean scores for survey items were compared
35 according to the error scenario and vignettes attributes. Significant differences were analysed using T
36 tests. Scale reliability was computed (Cronbach's Alpha) for the affective rating items for each error
37 scenario (N=7) and the mean scale score was calculated. Multiple regression analyses were performed
38 to examine the effect of vignette attributes and participants' characteristics (entered as predictor
39 variables) on attitudes towards family member's involvement. Sample size was calculated based on
40 recommendations for the use of regression analysis in behavioural research^{27,28}. Five regression
41 models were conducted for each error scenario (10 in total) relating to each of our key outcome
42 measures: 1) approval of family member's ~~behavior~~behaviour; 2) approval of HCPs response to the
43 family member; 3) support for being asked as a HCP; 4) positive effects on the family member-HCP
44 relationship, and; 5) the overall mean affective rating score. Chow-tests were performed to test if the
45 coefficients in the regression models for the medication error and hand hygiene scenarios were
46 significantly different or whether the models could be pooled. Data were screened for
47 multicollinearity and to ensure parametric assumptions were met. All tests were two-sided. We
48 considered $p < 0.05$ to be significant.
49
50
51
52
53
54
55
56
57
58
59
60

Results

Participant characteristics

In total, 209 HCPs were approached and 160 HCP completed the survey (77% response rate). 73 (46%) respondents were doctors, and 87 (54%) were nurses, aged between 21-65 years (mean = 37 years; SD = 10.4). 102 (64%) responders were female. Participants had on average 11 years of professional experience (SD = 10 years). HCPs that declined participation did so because they said they were too busy (N=40) or did not want to take part in the study (N=9).

Findings in relation to error frame

Across all scenarios, HCPs were supportive of the family member intervening (i.e. questioning the HCP) (mean approval score=5.8, CI 5.6-5.9). However, only 43.4% agreed that such behaviour would have positive effects on the family member-HCP relationship (responders with ratings >4). There were no significant differences in HCPs' responses to family members intervening in the medication error frame compared to the hand hygiene frame (Table 1).

Table 1 here

Affecting ratings scores

There was high internal consistency between HCPs' affective ratings scores (Cronbach's Alpha = 0.90). Thus composite scores were calculated (i.e. overall mean score of the seven affective ratings per person). There were no significant differences in the affective ratings or in the composite score in the medication error frame versus the hand hygiene frame. Doctors provided systematically more positive affective ratings as compared to nurses (Table 2).

Table 2 here

Correlations between affective rating scores and key outcome measures

HCPs' mean affective rating scores (composite measure) and responses to the 4 attitudinal judgments were only weakly correlated: Pearson's correlations revealed associations between HCPs' mean affective rating scores (composite measure) and responses to the 4 attitudinal judgments: I approve of the family members behaviour (r= 0.08, p=0.18); support for being asked as a HCP (r= 0.10, p=0.07); the HCP responded in the correct manner (r= 0.12, p=0.03); the situation would have positive effects on the family member-HCP relationship (r = 0.26, p<0.001). Thus, overall, Thus, HCPs were more

likely to expect positive effects on the family member-HCP relationship if they also perceived the HCP ~~behavior~~behaviour more ~~favorably~~favourably.

Results of the regression analyses

In multiple regression analyses, the impact of vignette attributes and respondents' characteristics on each of the survey questions were modelled. The results of the Chow tests revealed that the coefficients of the medication error and the hand hygiene models were not equal for three out of five outcomes measures (approval of behaviour; support of being asked as a HCP; affective rating composite score). Based on these findings we estimated separate models for the different error frames. The results of the regression analyses are displayed in Tables 3-5.

Tables 3-5 here

The single most important predictor variable in all models was the described HCP response to the family member intervening (variable nr 7 in the tables). A discouraging HCP response (as compared to an encouraging response) was associated with decreased approval and support of family member's behaviour and; affective ratings and had strong negative impact on the ~~effects on~~relation with the anticipated HCP-family member relationship. In both error frames, HCP reactions to the family member's behaviour ~~had large~~were strongly associated with ~~effects on~~ respondents' evaluations of whether the HCP responded in the right manner - a discouraging reaction was clearly judged negatively by participants.

The hypothetical family member's sex (variable nr 1) played a role in the evaluation of the interactions with staff (HCP response to being questioned and effects on the HCP-family member relationship) with male family members' interventions viewed being seen ~~less positively~~ by responders. Family member's sex contributed considerably to HCP's affective ratings but with opposite directions in the medication and hand hygiene frames. Irrespective of vignette attributes, affective ratings were more positive when the family member intervening was a male in the hand hygiene frame while they were higher for female family members in the medication error scenario.

Whether the family member intervening was a daughter/son of a senior patient or mother/father of a hospitalized child (variable nr 2) ~~had~~was only marginally and sporadically ~~sporadically associated~~ with the outcomes ~~measures~~.

~~only unsystematic and rather small effects.~~

1
2
3 When family members were described as intervening in a challenging rather than an inquiring way
4 [\(variable nr 5\)](#) this ~~only had~~ ~~had only~~ negative effects on approval and support of the behaviour in the
5 medication error frames. [In particular, it did not influence the affective ratings.](#)
6
7

8
9 The profession of the HCP involved in the interaction with the family member [\(variable nr 4\)](#)
10 impacted on the evaluations of the medication errors frames: The behaviour was more likely to be
11 approved and seen as positively affecting the relationship in scenarios in which the family member
12 intervened towards a doctor [rather than a nurse](#).
13
14

15
16 The attribution of error [\(variable nr 6\)](#) was an important predictor in the hand hygiene models in
17 particular. A false attribution of missed hand hygiene decreased approval and support of the behaviour
18 and also had negative ~~effects~~ ~~associations with~~ the anticipated HCP-family member relationship.
19 [Notably, A](#) false attribution of error had positive effects on the affective ratings in the medication
20 error frame.
21
22
23

24
25 Whether the situation was witnessed by another HCP [\(variable nr 3\)](#) ~~had~~ ~~was~~ only significantly
26 [associated with effects on](#) the affective ratings of the medication error frame [but not with any of the](#)
27 [other outcomes](#). The family member's behaviour was perceived less positive when the situation was
28 witnessed by ~~coworkers~~ [co-workers](#).
29
30
31

32 [In comparison to vignette attributes, personal characteristics of respondents \(variables 8-11\) had only](#)
33 [minor effects on their judgments:](#) Nurses as compared to doctors [\(variable nr 8\)](#) were significantly
34 more likely to approve of the family member's behaviour (in the hand hygiene scenarios) and support
35 the family member (both error frames). However, even after adjusting for vignette characteristics,
36 doctors were more likely to provide higher affective ratings as compared to nurses. Other
37 respondent's characteristics had only unsystematic and marginal effects on vignette ratings.
38
39
40
41

42 Discussion

43
44
45 This experimental vignette study set out to explore factors that influence HCPs' attitudes towards
46 family member's involvement in two safety-relevant areas; asking HCPs about their hand hygiene and
47 checking patients' medication. To our knowledge, this is the first study into the acceptance of family
48 members' ~~involvement in this area, intervening towards the safety of their loved ones in hospital.~~
49 Overall, we found a high level of support and approval for families intervening among surveyed
50 HCPs in both error scenarios. However, over all described situations 60% disagreed that the family
51 member's behaviour would have positive effects on the relationship with the HCP. Across vignette
52 attribute specifications, ~~there were~~ no differences between respondents' attitudes towards the hand
53 hygiene and the medication error frames [were observed](#). ~~Two factors in particular appeared~~ to have a
54
55
56
57
58
59
60

1
2
3 strong effect on attitudes – correct attribution of the error and how the HCP reacted to the family
4 member's involvement. Doctors (~~vs. nurses~~) ~~as compared to nurses~~ provided systematically more
5 positive affective ratings to the vignettes. In particular, they rated the hypothetical situations as easier
6 and more comfortable to manage and as less embarrassing.
7
8

9
10 We found some important differences to our previous studies on HCPs' acceptance of patient
11 involvement in safety^{23,24}. First, respondents' evaluations of the vignettes were only slightly and
12 unsystematically affected by how the family member intervened (challenging vs. inquiring).
13 Conversely however, our previous research revealed that patient behaviour was a strong predictor of
14 HCPs' approval; a finding also reflected in the wider literature. Garcia-Williams reported that HCPs
15 level of support in patients asking them about their hand hygiene would 'depend' on how they were
16 asked¹⁵. Second, HCPs in previous studies were much more positive about patient engagement in
17 medication safety and were more reluctant about involvement in hand hygiene. In this study, we
18 found some differences in attributes affecting outcomes measures (e.g., approval and affective
19 ratings), but only minor differences in overall level of support between medication error and hand
20 hygiene frames. Taken together, these results could potentially suggest that HCPs actually view
21 family involvement differently as it involves a different dynamic to the patient interacting with them.
22 Family engagement in safety seems to trigger less emotionally and strong responses by HCPs. The
23 fact, that the affective ratings were not as strong as in our previous studies also lends some support to
24 this hypothesis.
25
26
27
28
29
30
31
32
33

34 Another apparent difference between this study and prior research into HCP attitudes is that doctors in
35 our study provided more ~~favorable~~ favorable affective ratings than nurses. In previous research,
36 including those using similar vignettes, nurses were not only more willing to support being questioned
37 themselves about safety-related issues by patients^{23,24,29}, they also reported more positive affective
38 ratings^{23,24}. We can only speculate on the reasons for this finding. One explanation may be that
39 doctors less often experience situations in which family members question or challenge them. As a
40 consequence, they may underestimate the difficulty of ~~the his~~ situation and emotionally demanding
41 interactions.
42
43
44
45
46

47 This study is the first of its kind to provide insight into HCPs' acceptance of family members
48 questioning them about hand hygiene and medication safety-related concerns. A main strength is that
49 we used an experimental design to systematically manipulate factors and observe the effects of this
50 manipulation, something we would not be able to control for in observational studies. Still, direct
51 observation studies of family-HCP interactions relating to patient safety are warranted. This would
52 deepen our understanding of how, where, and by whom such interactions are initiated and how
53 satisfactory they are for HCP and family members. -A second strength is that we can directly explore
54
55
56
57
58
59
60

1
2
3 areas of agreement and differences between HCPs' attitudes towards patients' and family members'
4 involvement in patient safety. As we used the same factors and frames as in our previous studies, ~~we~~
5 ~~can directly explore areas of agreement and differences between HCPs' attitudes towards patients'~~
6 ~~and family members' involvement in patient safety.~~ Finally, the response rate to the survey is
7
8 reasonably good, in particular for a HCP sample.
9

10
11 The main limitation of our study is that we assessed attitudes and this is not always reflective of
12 behaviour. We thus do not know how participants in our study would in reality respond to families
13 engaging in the ~~for the~~ safety of their loved ones. We used "true life" vignettes to improve and
14 assimilate respondents' conceptions of family behaviour but the responses are still biased by
15 "hypotheticality". The sample is relatively small and the wider generalisability of our results needs to
16 be assessed in future studies. We also do not know whether any patient involvement activities in the
17 hospitals may have affected the results. Due to design and sample size reasons, we could not model
18 interactions of vignette attributes though these may be important for judgments about the scenarios.
19 Finally, it is worth noting that this was a cross-sectional study, therefore ~~and we we cannot can thus~~
20 ~~not make causal inferences about the relationships between variables.~~
21
22
23
24
25
26
27

28 This study serves only as an initial step into research in family engagement in safety. Today, very
29 little is known about family members attitudes and feelings about engagement, let alone strategies to
30 encourage involvement and whether families would be more willing to act on their loved ones behalf
31 than if they themselves were a patient in hospital. Future research is needed to enlighten the reasons
32 and motivations underlying the attitudes as expressed by HCPs in our study. The vignettes could serve
33 as a starting point in qualitative interview studies or focus groups with HCPs. Studies could use a
34 similar design to explore family members' attitudes towards involvement - this would be an
35 interesting parallel and is yet to be explored. It would be valuable to examine patients' perspectives on
36 their families intervening. There may be occasions where patients do not want their family members
37 to question staff. ~~—We also suggest studying the safety-related interactions between HCPs and family~~
38 ~~members in other medical settings, or even in comparison between settings, to gain a deeper~~
39 ~~understanding of the relevance of context. For example, we expect that family members of intensive~~
40 ~~care patients and the roles attributed to them may be viewed are probably being perceived very~~
41 ~~differently to other care settings due to patients often being unable to act for themselves in this~~
42 ~~context. HCPs in intensive care are also more used to being questioned and challenged by family~~
43 ~~members and may therefore experience less emotional distress when confronted by family members~~
44 ~~about safety-related issues. with safety-related interventions by family members.~~ Also, little is known
45 about the benefits and adverse effects of family involvement. While family members questioning
46 HCPs could result in positive effects (i.e. improved safety), the potential adverse consequences of
47 involving them remain unknown, e.g. it could potentially heighten anxiety, placing inappropriate
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 responsibility on them when they are already worried about their loved, or it could make them fear if
4 they do not question HCPs the patient will be at increased risk. It may also create tensions in their
5 relationship with HCPs - though our results do not seem to indicate this.
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

For peer review only

1
2
3
4
5
6
7
8 **Acknowledgements:** We thank the research participants for their time in completing our survey.
9

10
11 **Contributorship statement:** DS conceptualised the study and designed the survey instrument with
12 the assistance of RD. RD monitored data collection and entry for the survey and DS analysed data.
13 Both RD and DS drafted and revised the paper. RD is guarantor and affirms this is an honest and
14 transparent account of the study being reported; that no important aspects of the study have been
15 omitted, and that; any discrepancies from the study have been explained. MS, RS and SS collected the
16 data and provided feedback on the paper. All authors had full access to all of the data (including
17 statistical reports and tables) in the study and can take responsibility for the integrity of the data and
18 the accuracy of the data analysis.
19

20
21 **Competing interests:** *"All authors have completed the Unified Competing Interest form at*
22 *www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author Rachel Davis)*
23 *and declare that (1) RD, MS, RS, SS, and DS have support from Imperial College London for the*
24 *submitted work; (2) have no relationships with companies that might have an interest in the submitted*
25 *work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships*
26 *that may be relevant to the submitted work and; (4) have no non-financial interests that may be*
27 *relevant to the submitted work"*
28

29
30 **Funding:** The Clinical Safety Research Unit is affiliated with the Centre for Patient Safety and
31 Service Quality at Imperial College Healthcare NHS Trust which is funded by the National Institute
32 of Health Research. The opinions expressed are those of the authors and do not necessarily reflect the
33 policies or views of the National Institute of Health Research. The NIHR played no role in the study
34 design; collection, analysis, and interpretation of data; writing of the manuscript; or the decision to
35 submit the article for publication. Researchers were independent of influence from the NIHR.
36

37
38 **Data sharing:** Informed consent to participate in the study was gained from all research participants.
39 The data presented in this manuscript are anonymised thus there is no risk of participant
40 identification. There is no additional data available.
41

42
43 **Ethical approval:** The study was considered by the Chair of Hampstead's National Research Ethics
44 Committee and classified as exempt from review.
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

References

1. World Health Organisation (WHO). Quality of Care: Patient Safety. Fifty-fifth World Health Assembly, 2002. <http://www.who.int/patientsafety/worldalliance/ea5513.pdf?ua=1>
2. WHO Guidelines on Hand Hygiene in Health Care. First Global Patient Safety Challenge Clean Care is Safer care, 2009
http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf?ua=1
3. WHO. Global priorities for research in patient safety (first edition). The Research Priority Setting Working Group, 2008.
http://www.who.int/patientsafety/research/priorities/global_priorities_patient_safety_research.pdf
4. Vincent C, Coulter A. Patient safety: what about the patient? *Quality and Safety in Healthcare*, 2002; 11: 76-80.
5. Coulter A, Ellins J. Patient-focused interventions: A review of the evidence. Chapter 4 'Improving patient safety', pgs 143-178. Health Foundation, 2006.
6. Schwappach D. Engaging patients as vigilant partners in safety. A systematic review. *Medical Care Research and Review*, 2010; 67:2: 119-148
7. Lawton R, Armitage G. The role of the patient in clinical safety. Health Foundation, 2012.
8. WHO. Exploring patient participation in reducing healthcare-related safety risks. WHO, 2013
http://www.euro.who.int/_data/assets/pdf_file/0010/185779/e96814.pdf
9. Davis R, Sevdalis N, Jacklin R, Vincent C. An examination of opportunities for the active patient in improving patient safety. *Journal of Patient Safety*, 2012; 8:1:36-43.
10. Davis R, Vincent C, Murphy M. Blood transfusion safety: The potential role of the patient. *Transfusion Medicine Reviews*, 2011; 25:1:12-23.
11. Davis R, Sevdalis N, Vincent C. Patient involvement in patient safety- How willing are patients to participate? *BMJ Quality and Safety*, 2011; 20:108-114.
12. Unruh KT, Pratt W. Patients as actors: the patient's role in detecting, preventing, and recovering from medical errors. *International Journal of Medical Informatics* 2007; 76(Suppl 1):S236-44.
13. Davis R, Koutantji M, Vincent C. How willing are patients to question healthcare staff on issues related to the quality and safety of their healthcare? An exploratory study, *Quality and Safety in Health Care*, 2008. 17; 90-96.

- 1
2
3 14. Longtin, Y et al. 2009. Patients' beliefs and perceptions of their participation to increase
4 healthcare worker compliance with hand hygiene. *Infection Control and Hospital*
5 *Epidemiology*, 2009; 30:9: 830-839.
- 6
7
8 15. Garcia-Williams A, Brinsley-Rainisch K, Schille S, Sinkowitz-Cochran R. To ask or not to
9 ask? The results of a formative assessment of a video empowering patients to ask their health
10 care providers to perform hand hygiene. *Journal of Patient Safety*, 2010; 6:2: 80-85.
- 11
12 16. Hibbard J, Peters E, Slovic P, Tusler M. 2005. Can patients be part of the solution? Views on
13 their role in preventing medical errors. *Medical Care Research and Review* 2005; 62: 601-
14 616.
- 15
16
17 17. Marella, W. M. et al. (2007). Healthcare consumers' inclination to engage in selected patient
18 safety practices: a survey of adults in Pennsylvania. *Journal of Patient safety*, 3, 184-189.
- 19
20 18. Pittet D, Panesar SS, Wilson K, et al. Involving the patient to ask about hospital hand
21 hygiene: a National Patient Safety Agency feasibility study *Journal of Hospital Infection*
22 2011; 77: 299-303.
- 23
24 19. Ottum A, Sethi AK, Jacobs EA, Zerbal S, Gaines ME, Safdar N. Do patients feel comfortable
25 asking healthcare workers to wash their hands? *Infection Control and Hospital Epidemiology*,
26 2012; 33:12:1282-1284
- 27
28 20. Michealson K, Sanders JL, Zimmer SM, Bump GM. Overcoming patient barriers to
29 discussing physician hand hygiene: do patients prefer electronic reminders to other methods?
30 *Infection Control and Hospital Epidemiology*, 2013; 34:9:929-934.
- 31
32 21. Julian K, Subramanian K, Brumbach A, Whitener CJ. Attitudes of healthcare workers and
33 patients towards individualised hand hygiene reminders. *Infection Control and Hospital*
34 *Epidemiology*, 2008; 29:8:781-782.
- 35
36 22. WHO Alliance for Patient Safety Hand Hygiene Survey Results from Phase One October
37 2007 http://www.who.int/patientsafety/hand_hygiene_survey.pdf
- 38
39 23. Davis R, Briggs M, Arora S, Schwappach D. Predictors of healthcare professionals' attitudes
40 towards involvement in safety-related behaviours. *Journal of Evaluation and Clinical Practice*,
41 2014; 20:1:12-9.
- 42
43 24. Schwappach D, Davis R, Frank O. A vignette study to examine healthcare professionals'
44 attitudes toward patient involvement in error prevention. *Journal of Evaluation and Clinical*
45 *Practice*, 2013;19:5:840-8
- 46
47 25. Schwappach DL, Hochreutener MA, Wernli M. Oncology nurses' perceptions about involving
48 patients in the prevention of chemotherapy administration errors. *Oncol Nurs Forum* 2010;
49 37:2:E84-E91.
- 50
51 26. Bradley M. Users manual for SPEED. version 2.1 stated preference editor and designer. The
52 Hague: Hague Consulting Group; 1991.
- 53
54
55
56
57
58
59
60

- 1
- 2
- 3 27. Park C, Dudycha A. A cross-validation approach to sample size determination. *Journal of the*
- 4 *American Statistical Association*, 1974; 69: 214-218.
- 5
- 6 28. Pedhazur EJ. *Multiple regression in behavioral research*. Harcourt Brace: Orlando, FL, 1997.
- 7
- 8 29. Davis RE, Sevdalis N, Vincent CA. Patient involvement in patient safety: the health-care
- 9 professional's perspective. *Journal of Patient Safety*, 2012;8:4:182-8
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26
- 27
- 28
- 29
- 30
- 31
- 32
- 33
- 34
- 35
- 36
- 37
- 38
- 39
- 40
- 41
- 42
- 43
- 44
- 45
- 46
- 47
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

For peer review only

Tables and boxes

Box 1: Example vignettes

Factor	Levels with coding
A Family member's sex	0: Female 1: Male
B Relation to patient	0: Parent to patient 1: Child of patient
C Situation witnessed	0: No, patient and HCP are alone 1: Yes, event is witnessed by other HPC
D Staff occupation	0: Nurse 1: Doctor
E Patient's behavior behaviour	0: Inquiring 1: Challenging
F Attribution of error	0: True, HCP did make an error 1: False, HCP did not make an error
G Staff response	0: Encouraging 1: Discouraging

Error scenario 1, vignette A₀B₀C₁D₁E₀F₀G₁

Mrs Smith is mother to a five year old boy. Mrs Smith's son has been in hospital for a few days. He had a complicated appendectomy. Mrs Smith is present at hospital daily to watch after her son. During the morning several doctors and nurses enter the room. A doctor inspects the wound dressing of Mrs Smith's son. Mrs Smith looks anxious and asks: *excuse me, shouldn't you need to wash your hands?* As it is a very busy morning the doctor had in fact forgot to wash his hands. The doctor rolls his eyes and disinfects his hands using alcohol gel.

Error scenario 2, vignette A₁B₀C₀D₁E₁F₀G₀

Mr Brown is father to a five year old boy. Mr Brown's son has been in hospital for a number of days. He is suffering from severe heart problems. Mr Brown is present at hospital daily to watch after his son. His son has been prescribed several drugs. Early this morning, the nurse gave the medication to Mr Brown and instructed him that his son should take them with breakfast. Later on in the morning a doctor enters the room. The doctor asks Mr Brown's son how he is doing. Mr Brown looks angry and states: *Can you please check these red tablets. I do not think these are meant to be for my son!* The doctor had been very busy when writing prescriptions yesterday and had been interrupted several times. The doctor checks the medication against the chart and says: *'oh yes it is very good that you ask. I am really sorry it seems that your son indeed has been given the wrong medication. Your prescription should not have changed.*

Note: letters in Box 1 indicate factors and numbers in superscripts represent the levels

Table 1. Results in relation to error frame (N=160)

Outcome measure (survey questions)	Error scenario*		
	Hand hygiene Mean, [CI]	Medication error Mean, [CI]	p
I approve of the family member's behaviour	5.9 [5.6,6.1]	5.7 [5.4,5.9]	0.2589
The HCP responded in the right manner	4.8 [4.5,5.2]	4.7 [4.3,5.0]	0.5015
The situation would have predominantly positive effects on the caregiver-HCP relationship	4.0 [3.7,4.4]	3.8 [3.5,4.2]	0.3852
I would as a HCP support the caregiver asking me	6.0 [5.8,6.2]	6.0 [5.8,6.2]	0.9650

*Level of agreement was measured on a 7-point Likert response scale with higher numbers indicating higher levels of agreement.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49

Table 2. Results of affective ratings scores (N=160)

Affective items	Mean rating* [CI]			p
	Total	Doctors	Nurses	
Bad-Good	3.6 [3.4,3.8]	4.0 [3.7,4.2]	3.4 [3.1,3.7]	0.0041
Difficult-Easy	3.7 [3.5,3.9]	4.1 [3.8,4.3]	3.3 [3.1,3.6]	0.0001
Confrontational -Not confrontational	3.9 [3.7,4.1]	4.2 [3.9,4.5]	3.7 [3.4,4.0]	0.0243
Not helpful - Very helpful	4.7 [4.6,4.9]	4.8 [4.6,5.0]	4.7 [4.4,4.9]	0.4661
Very embarrassing-Not embarrassing	3.8 [3.5,4.0]	4.3 [4.0,4.6]	3.3 [3.0,3.6]	<0.0001
Challenging -Not challenging	4.1 [3.9,4.3]	4.4 [4.1,4.7]	3.8 [3.5,4.1]	0.0040
Very uncomfortable-Comfortable	3.6 [3.4,3.8]	4.1 [3.8,4.3]	3.2 [2.9,3.5]	<0.0001
Composite, affective score**	3.9 [3.8,4.1]	4.2 [4.0,4.5]	3.6 [3.4,3.8]	0.0001

*A 7-point response scale was used with the semantic differentials serving as anchor labels (higher scores indicating more favourable responses)
 ** Mean over the seven ratings per person

Peer review only

Table 3. Results of multiple regression analyses (N=160)

Variable nr	Vignette attributes	Approval of family member's behaviour						The HCP responded in the right manner					
		HH Error Vignettes			Medication Error vignettes			HH Error Vignettes			Medication Error vignettes		
		Coeff	95% CI	p	Coeff	95% CI	p	Coeff	95% CI	p	Coeff	95% CI	p
1	Family member gender (1=male)	0.047	-0.383,0.477	0.830	-0.042	-0.422,0.337	0.825	-0.779	-1.321,-0.236	0.005	-0.403	-0.881,0.075	0.098
2	Relation to patient (1=daughter/son of patient)	-0.251	-0.679,0.177	0.249	-0.436	-0.813,-0.058	0.024	0.232	-0.308,0.772	0.398	0.015	-0.462,0.491	0.952
3	Situation witnessed (1=yes)	0.056	-0.385,0.496	0.803	-0.319	-0.692,0.053	0.092	-0.072	-0.627,0.483	0.799	0.299	-0.171,0.769	0.210
4	Staff occupation (1=doc)	0.110	-0.316,0.535	0.611	0.429	0.037,0.820	0.032	0.226	-0.310,0.763	0.406	0.621	0.126,1.115	0.014
5	Family member behavior/behaviour (1=challenging)	-0.384	-0.808,0.040	0.076	-1.362	-1.737,-0.987	0.000	0.386	-0.149,0.920	0.156	-0.210	-0.683,0.263	0.382
6	Attribution of error (1=false)	-1.033	-1.471,-0.594	0.000	-0.683	-1.059,-0.306	0.000	-0.779	-1.331,-0.226	0.006	-0.422	-0.897,0.053	0.081
7	Staff response (1=discouraging)	-0.583	-1.013,-0.153	0.008	-0.756	-1.143,-0.370	0.000	-2.799	-3.341,-2.257	0.000	-3.119	-3.606,-2.632	0.000
	Respondents' characteristics												
8	Doctor or nurse (1=nurse)	0.520	0.040,1.000	0.034	0.083	-0.340,0.506	0.699	0.498	-0.107,1.103	0.106	0.355	-0.179,0.889	0.191
9	Age, years	0.008	-0.038,0.054	0.726	-0.034	-0.075,0.006	0.097	-0.024	-0.082,0.034	0.410	0.010	-0.041,0.062	0.686
10	Sex (1=female)	0.019	-0.488,0.525	0.942	-0.092	-0.539,0.355	0.686	-0.731	-1.370,-0.092	0.025	-0.343	-0.907,0.220	0.231
11	Years of experience, years	-0.016	-0.065,0.034	0.534	0.048	0.005,0.092	0.030	0.011	-0.052,0.073	0.739	-0.033	-0.088,0.022	0.237
12	constant	6.449	4.875,8.022	0.000	8.010	6.741,9.278	0.000	7.596	5.612,9.580	0.000	6.261	4.661,7.861	0.000
	R-sqr	0.229			0.400			0.467			0.581		
	overall model p	<0.001			<0.001			<0.001			<0.001		

Table 4. Results of multiple regression analyses (N=160)

Variable nr	Vignette attributes	Positive effects on the family member/HCP relationship						Support for being asked as a HCP					
		HH Error Vignettes			Medication Error vignettes			HH Error Vignettes			Medication Error vignettes		
		Coeff	95% CI	p	Coeff	95% CI	p	Coeff	95% CI	p	Coeff	95% CI	p
1	Family member gender (1=male)	-0.523	-1.072,0.026	0.062	-0.596	-1.073,-0.120	0.015	-0.308	-0.676,0.060	0.101	-0.120	-0.508,0.267	0.540
2	Relation to patient (1=daughter/son of patient)	0.321	-0.226,0.867	0.248	0.038	-0.437,0.512	0.875	0.389	0.023,0.756	0.038	-0.195	-0.581,0.191	0.320
3	Situation witnessed (1=yes)	0.045	-0.517,0.607	0.874	0.132	-0.336,0.600	0.577	0.293	-0.084,0.669	0.127	-0.186	-0.566,0.195	0.336
4	Staff occupation (1=doc)	0.050	-0.493,0.593	0.856	0.760	0.267,1.252	0.003	0.395	0.031,0.759	0.034	0.072	-0.329,0.472	0.724
5	Family member behavior/behaviour (1=challenging)	-0.127	-0.668,0.413	0.642	-0.454	-0.926,0.017	0.059	0.225	-0.138,0.587	0.223	-0.432	-0.815,-0.048	0.028
6	Attribution of error (1=false)	-0.943	-1.502,-0.384	0.001	0.098	-0.375,0.571	0.683	-0.725	-1.100,-0.350	0.000	0.162	-0.223,0.547	0.408
7	Staff response (1=discouraging)	-2.245	-2.794,-1.697	0.000	-2.420	-2.905,-1.934	0.000	-0.509	-0.877,-0.141	0.007	-0.379	-0.774,0.016	0.060
Respondents' characteristics													
8	Doctor or nurse (1=nurse)	0.400	-0.212,1.012	0.199	0.172	-0.360,0.703	0.524	0.490	0.079,0.900	0.020	0.580	0.148,1.013	0.009
9	Age, years	-0.004	-0.063,0.055	0.897	-0.003	-0.054,0.048	0.915	-0.007	-0.047,0.032	0.711	0.005	-0.037,0.046	0.821
10	Sex (1=female)	-0.377	-1.024,0.269	0.251	-0.135	-0.696,0.427	0.636	-0.139	-0.573,0.294	0.527	-0.153	-0.610,0.303	0.508
11	Years of experience, years	-0.011	-0.074,0.052	0.733	-0.019	-0.074,0.035	0.488	-0.005	-0.048,0.037	0.802	0.003	-0.041,0.048	0.893
12	constant	6.043	4.035,8.051	0.000	5.374	3.780,6.968	0.000	6.297	4.950,7.644	0.000	6.135	4.839,7.431	0.000
	R-sqr	0.377			0.484			0.255			0.124		
	overall model p	<0.001			<0.001			<0.001			0.042		

Table 5. Results of multiple regression analyses (N=160)

		Affective ratings scores					
		Hand hygiene vignettes			Medication error vignettes		
		Coeff	95% CI	p	Coeff	95% CI	p
Variable nr	Vignette attributes						
1	Family member gender (1=male)	0.786	0.414,1.159	0.000	-0.846	-1.198,-0.493	0.000
2	Relation to patient (1=daughter/son of patient)	0.015	-0.356,0.386	0.935	0.415	0.064,0.767	0.021
3	Situation witnessed (1=yes)	0.179	-0.203,0.560	0.356	-0.369	-0.715,-0.022	0.037
4	Staff occupation (1=doc)	-0.048	-0.417,0.321	0.797	0.170	-0.195,0.534	0.359
5	Family member behavior <u>behaviour</u> (1=challenging)	0.108	-0.260,0.475	0.564	-0.158	-0.506,0.191	0.374
6	Attribution of error (1=false)	-0.336	-0.716,0.044	0.083	1.288	0.938,1.638	0.000
7	Staff response (1=discouraging)	-1.062	-1.435,-0.690	0.000	-0.592	-0.952,-0.233	0.001
Respondents' characteristics							
8	Doctor or nurse (1=nurse)	-0.525	-0.941,-0.109	0.014	-0.359	-0.753,0.034	0.073
9	Age, years	0.025	-0.015,0.065	0.226	0.017	-0.021,0.055	0.378
10	Sex (1=female)	-0.113	-0.552,0.327	0.613	-0.327	-0.743,0.089	0.122
11	Years of experience, years	-0.019	-0.062,0.024	0.375	-0.012	-0.052,0.029	0.572
12	constant	3.772	2.408,5.136	0.000	3.824	2.644,5.005	0.000
	R-sqr	0.320			0.439		
	overall model p	<0.001			<0.001		

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	5,6
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6,7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6,7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	7
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	7
		(b) Describe any methods used to examine subgroups and interactions	7
		(c) Explain how missing data were addressed	NA
		(d) If applicable, describe analytical methods taking account of sampling strategy	NA
		(e) Describe any sensitivity analyses	7
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	8-10
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	17-21 in tables
		(b) Report category boundaries when continuous variables were categorized	8-10,17-21
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8-10,17-21
Discussion			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-11
Generalisability	21	Discuss the generalisability (external validity) of the study results	10-11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	4

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.