

Original Research Article

# Development of the perceptions of preventable adverse events assessment tool (PPAEAT): measurement properties and patients' mental health status

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## Abstract

**Background:** Patient-centered care and patient involvement have been increasingly recognized as crucial elements of patient safety. However, patient safety has rarely been evaluated from the patient perspective with a quantitative approach aiming at making patient safety and preventable adverse events measurable.

**Objectives:** The objectives of this study were to develop and evaluate the psychometric properties of a questionnaire assessing patient safety by perceived triggers of preventable adverse events among patients in primary health-care settings while considering mental health.

**Methods:** Two hundred and ten participants were recruited through various digital and print channels and asked to complete an online survey between November 2019 and April 2020. Exploratory factor analysis was performed to identify domains of triggers of preventable adverse events affecting patient safety. Furthermore, a multi-trait scaling analysis was performed to evaluate internal reliability as well as item-scale convergent–discriminant validity. A multivariate analysis of covariance evaluated whether individuals below and above the symptom threshold for depression and generalized anxiety perceive triggers of preventable adverse events differently.

**Results:** The five factors determined were information and communication with patients, time constraints of health-care professionals, diagnosis and treatment, hygiene and communication among health-care professionals, and knowledge and operational procedures. The questionnaire demonstrated a good total and subscale internal consistency ( $\alpha = 0.90$ , range = 0.75–0.88), good item-scale convergent validity with significant correlations between 0.57 and 0.78 ( $P < 0.05$ ;  $P < 0.01$ ) for all items with their associated subscales, and satisfactory item-scale discriminant validity between 0.14 and 0.55 ( $P > 0.05$ ) with no significant correlations between the items and their competing subscales. The questionnaire further revealed to be a generic measure irrespective of patients' mental health status. Patients older than 50 years of age perceived a significantly greater threat to their own safety compared to patients below that age.

**Conclusion:** The developed Perceptions of Preventable Adverse Events Assessment Tool (PPAEAT) exhibits good psychometric properties, which supports its use in future research and primary

health-care practice. Further validation of the PPAEAT in different settings, languages and larger samples is needed. The results of this study need to be considered when assessing patient safety in the context of health-care research.

**Key words:** patient safety, preventable adverse events, mental health disorders, age, psychometric properties

## Introduction

Research into human factors in health and patient safety in primary care settings has increasingly gained importance, especially concerning the patient perspective [1]. Patient safety is a central goal of health care [2] and has been defined as the absence of adverse events. Sandars and Esmail reported in their review that the occurrence of patient safety incidents in primary care settings is between 5 and 80 per 100 000 consultations in Australia and in the USA [3]. Several studies have determined key domains of patient safety and defined areas of re-occurring preventable adverse events (pAEs [4–6]). Common agreed domains were diagnosis and treatment, organization of health care, human factors of health-care professionals, teamwork and effective communication between health-care professionals, the patient role and patient–provider communication as well as environment and (technical) equipment in care settings [7].

pAEs as relevant factors of patient safety have been defined as a potentially harmful result of care that fell below the standard expected in a certain setting [8]. Most knowledge on the prevalence of pAEs in hospital settings has been obtained from retrospective reviews of patient records, formal incident reporting or case studies [9–11]. While these results often show the pAE or negative consequence itself, they rarely highlight the potential processes or triggers that lead to pAEs.

Former research highlighted the importance of assessing the needs of patients and what matters most to patients with regard to their own safety [12]. If patient needs are not properly understood, this missing knowledge can pose an additional threat to patient safety. Patients may experience considerable trauma because of pAEs and their inadequate management [13]. Therefore, patient involvement needs to be considered more systematically to reduce errors as well as to increase transparency about what constitutes patient safety while also providing tailored treatment options [6, 14]. While there has already been some research into qualitative evaluations of patient safety, there is still a lack of understanding concerning the patients' experience in care settings and quantitative research on triggers of pAEs has been limited [15].

Literature has proposed that mental health in terms of generalized anxiety and depression can be associated with a number of illnesses and various health-related processes such as the burden of physiological medical symptoms [16], treatment, recovery as well as readmission [17]. However, a big gap remains in the current literature on whether and how patients' anxiety and depressive symptoms are associated with the perception of their own safety.

Thus, the research objectives of this study are to close this research gap by [1] developing a questionnaire that assesses perceived triggers of pAEs in health-care settings from the patient perspective [2], evaluating the psychometric properties in terms of factor structure of the questionnaire as well as reliability and item-scale convergent-discriminant validity, and [3] determining whether the questionnaire is a generic measure and, thus, appropriate for patients with and without clinical psychological symptoms.

## Methods

### Procedure

Participants were recruited through various channels such as press releases, social networks and through study homepages. Data were collected anonymously with the online survey tool Unipark between November 2019 and April 2020. The survey lasted for 10 min. All participants were informed about the purpose of the survey and provided online informed consent.

### Instruments

#### *Patient safety and preventable adverse events—questionnaire development*

Items assessing triggers of preventable adverse events (pAEs) derived from a literature research of reviews, syntheses, incident and case reports, patient-reported outcome measures and patient-reported experience measures, which measure the outcomes of patient health and the experience about a caring process [5, 6, 9, 18, 19]. An item pool of 47 items assessing potential triggers was developed and refined by two chief medical officers and doctors from the field of gynecology and obstetrics, psychologists as well as quality management staff with over 15 years of work experience from two university hospitals. After initial piloting and adaptation, participants were asked to estimate whether they have experienced triggers of pAEs during their last hospital visit (1 = 'completely disagree', 2 = 'somewhat disagree', 3 = 'somewhat agree' and 4 = 'completely agree'). Higher average ratings denote a more common threat to patient safety.

#### *Depressive symptoms*

The PHQ-9 is the depression module of the Patient Health Questionnaire, which is a self-administered questionnaire assessing each of the nine Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria for depression on a 4-point Likert scale from 0 ('not at all') to 3 ('nearly every day'). A sum score of  $\geq 10$  depicts the cutoff value with a sensitivity of 88% and specificity of 88%. The scale has a Cronbach's alpha of 0.89 in care settings [20].

#### *Generalized anxiety symptoms*

The GAD-7, a self-report measure of generalized anxiety disorder symptoms, measures seven items based on the seven DSM-5 criteria on a 4-point Likert scale from 0 ('not at all') to 3 ('nearly every day'). A sum score of  $\geq 10$  represents the cutoff value and provides a sensitivity of 89% and specificity of 82%. Primary validation estimated a Cronbach's alpha of 0.86 [21].

#### *Sociodemographic and additional information*

Additional data included patients' age, sex and last admission as an inpatient or outpatient to a hospital. All variables were treated as categorical variables.

### Data analysis

Missing values were imputed via multiple imputations within SPSS Version 26. Five datasets were created and combined via the Output Management System (OMS procedure) into one dataset. Firstly, an exploratory factor analysis (EFA) was carried out to determine factor structure and factor loadings. Three sequential steps were taken. Step 1 involved identifying the number of meaningful factors to retain based on the scree plot and the percentage of (common) variance explained by a given factor with an eigenvalue of above 1. Factors that appeared to be meaningful were retained for rotation. Promax (oblique) rotation was applied during Step 2 on the retained factors. Oblique rotation was chosen and considered appropriate because the factors retained for further analyses were constructs of the overall construct of patient safety and, thus, reasoned to be significantly correlated with one another. Identification and interpretation of the factor loadings of relevant items retained were performed in Step 3. Item loadings  $>0.40$  were used for interpretation purposes. Hence, 27 items were eliminated for the analysis due to low item loadings.

As part of the multi-trait scaling analysis, internal consistency and reliability of the scales were examined by assessing the item-scale correlation to test whether the item was correlated with the hypothesized scale. An item-scale correlation of  $<0.40$  was considered as low so that the item was removed from the respective scale. An item internal consistency value of  $\geq 0.40$  can, thus, be considered satisfactory. A narrow range of item-scale correlation within each defined scale was used as an assessment to confirm the choice between item and hypothesized scale. A range of  $<0.20$  was defined as acceptable. A Cronbach's alpha value between 0.70 and 0.90 was considered as satisfactory [22].

Furthermore, item-concurrent and item-divergent validity were analyzed by means of a multi-trait scaling analysis. The multi-trait scaling analysis allows for the following assumptions to be tested simultaneously [1]: Item-subscale consistency (correcting for overlap) [2], equality of item-scale correlation and [3] item-scale convergent-discriminant validity. Item-subscale consistency considers the correlations between an item and the subscale score computed from all other items associated with the same subscale by assessing Cronbach's alpha (correcting for overlap). By this, an inflation of the item-scale correlation is avoided. Next to the test of item-subscale consistency, the second assumption is considering the equality of item-scale correlations. This requires items of the same subscale to contribute roughly equal proportions of information to the total subscale score. Item-scale convergent-discriminant validity assesses whether an item measures what it is supposed to measure, but also the extent to which an item is associated with other competing subscales that it is not supposed to be associated with. Item-scale discriminant validity was analyzed by evaluating Pearson's correlation coefficient. Concerning item-scale discriminant validity, the standard significance level used to compare two correlations is considered to be two standard errors (standard errors of a correlations coefficient represented by 1 divided by the square root of the total sample size).

In addition, multivariate analyses of covariance were performed to test for differences in perceived patient safety between mentally healthy and non-healthy groups of patients with depressive as well as symptoms of generalized anxiety. All data analysis was carried out using IBM SPSS Version 26.

## Results

### Participants

Two hundred and ten participants completed an online questionnaire. One hundred and forty-four participants (68.6%) were female, and

19 (9.0%) did not indicate their gender. The participants varied in age from 18 to over 60 years old. Sixty-eight (32.4%) participants indicated that they were admitted to the hospital during the last year, 75 (35.7%) during the last 1–5 years and 51 (24.3%)  $\geq 5$  years ago. One hundred and fifty-nine (75.7%) participants revealed no depressive symptoms while 51 (24.3%) participants showed depressive symptoms according to the threshold by Kroenke and colleagues [20]. One hundred and seventy-eight (84.8%) participants reported no symptoms of generalized anxiety whereas 32 (15.2%) reported symptoms above the threshold according to Spitzer and colleagues [21].

### Exploratory factor analysis

The original missing data analysis revealed missing data of 4.65%. As a summated rating score for each subscale cannot be estimated with the same degree of confidence with missing data, multiple imputations were performed prior to the analyses on missing data concerning measures of pAEs. All 47 items were subjected to the exploratory factor analysis. After oblique rotation, 20 items were retained in the analysis with a factor loading of  $\geq 0.40$  with the respective factor (Table 1).

Five factors could explain 70.3% variance. Items on the first factor (4 items) represented information and communication with patients, items on the second factor (5 items) represented the time constraints of health-care professionals, items on the third factor (4 items) represented diagnosis and treatment process, items on the fourth factor (3 items) highlighted hygiene and communication among healthcare professionals and the fifth factor (4 items) centered around knowledge and operational procedures.

### Item descriptive statistics

Table 2 depicts mean scores with standard deviations and frequency distributions of average answer patterns of the 20 items. The frequency distribution expresses the degree of agreement with potential triggers of prevalent adverse events. The most commonly perceived threat to patient safety was found within the factor of time constraints of health-care professionals with an average mean of  $M = 2.77$  ( $SD = 0.73$ ). Knowledge and operational procedures were perceived by patients to pose a rather uncommon threat to patient safety ( $M = 1.79$ ,  $SD = 0.65$ ). For item means per factor see Table 2.

### Multi-trait scaling analysis

Results of the multi-item correlation matrix are shown in Table 3. Each row in the matrix contains Pearson's correlations between the score for an item and all five hypothesized item groupings. Each column contains correlations between the total score for one subscale and all items in the matrix.

Results concerning item-subscale consistency reveal that all items on all five factors show a value of  $\geq 0.40$  with the respective subscale, hence meeting the assumption of item-subscale consistency. All five subscales meet the criteria for the assumption of equality of item-scale correlations. As shown in Table 3, the range of all item-scale correlations within each defined scale was lower than the previously defined value of  $<0.20$ . Furthermore, item-convergent validity (item scale correlation  $\geq 0.40$ ) and item-scale discriminant validity (an item-own scale correlation higher than the correlation with the other competing subscales) were termed as sufficient as all items had higher correlations with their hypothesized own scales than with the other competing scales (see Table 3).

**Table 1** Exploratory factor analysis—factor loadings and explained variance ( $N = 210$ )

Scale/ Item	Label	1	2	3	4	5
Scale 1 = Information and communication with patients						
IC1	Not informed about procedure beforehand	0.72				
IC2	Not sufficiently informed about medications and side effects	0.70				
IC3	Not adequately informed about treatment procedure	0.65				
IC4	Not sufficiently informed overall	0.64				
Scale 2 = Time constraints						
TC1	A lack of health-care professionals available		0.88			
TC2	Long waiting times		0.84			
TC3	Many delays		0.77			
TC4	A lack of time of health-care professionals		0.69			
TC5	The health-care professionals seemed emotionally burdened		0.64			
Scale 3 = Diagnosis and treatment						
DT1	Diagnoses were incorrect			0.90		
DT2	Diagnoses were made too late			0.83		
DT3	The treatment proposed was not sufficient			0.80		
DT4	Diagnoses were made too hastily			0.80		
Scale 4 = Hygiene and communication among health-care professionals						
HC1	Lack of hand hygiene among health-care professionals				0.80	
HC2	Conflicts among the hospital staff				0.71	
HC3	The health-care professionals were not sufficiently informed				0.66	
Scale 5 = Knowledge and operational procedures						
KP1	The hospital was not operating at current state of art					0.82
KP2	The health-care professionals were not well versed in technical equipment					0.69
KP3	The health-care professionals seemed uncertain					0.67
KP4	Equipment in the examination rooms was missing					0.65

*Abbreviations:* IC = Information and communication with patients, TC = Time constraints, DT = Diagnosis and treatment, HC = Hygiene and communication among health-care professionals, KP = Knowledge and operational procedures.

### Reliability and correlation between subscales

Results from [Table 4](#) reveal acceptable Cronbach's alpha coefficients between 0.75 and 0.88, which are below the recommended acceptable maximum value of 0.90 and above the suggested value of 0.70. Furthermore, all correlation coefficients between two subscales are consequently lower than their reliability coefficients. All correlations among subscales were significantly related to each other ( $P < 0.01$ ). The total internal consistency proved to be good ( $\alpha = 0.90$ ).

### Multivariate analyses of covariance with depression and generalized anxiety

To examine whether participants below and above the threshold for generalized anxiety and depressive symptoms differed in their perception of triggers of pAEs, multivariate analyses were performed controlling for gender, age and last hospital visit. Results indicate generic patterns regarding perceived triggers of pAEs in participants below and above the threshold for depressive symptoms ( $F(5,182) = 0.57, P = 0.72$ ) as well as generalized anxiety symptoms ( $F(5,182) = 0.86, P = 0.51$ ; [Figure 1](#)).

However, triggers of pAEs differed concerning age groups ( $F(1,191) = 15.62, P < 0.001$ ). Patients below the age of 50 years perceived a significantly lower threat to their safety ( $M = 42.06, SD = 10.89$ ) compared to participants above that age ( $M = 48.28, SD = 9.18$ ).

## Discussion

### Statement of principal findings

The current study with 210 participants aimed to develop a questionnaire assessing potential triggers of preventable adverse events

that indicate patient safety concerns from the patient perspective. Therefore, psychometric properties were investigated. As a secondary aim, we evaluated whether the PPAEAT questionnaire is robust against effects of the mental health status. The results of the present study provide evidence for the psychometric properties (internal consistency, reliability and item-scale convergent-discriminant validity) of Perceptions of Preventable Adverse Events Assessment Tool (PPAEAT) assessing perceived triggers of pAEs that is useful for both patients with and without symptoms of depression and generalized anxiety.

The factor structure identifies five different areas of pAEs from the patient perspective: information and communication with patients, time constraints of health-care professionals, diagnosis and treatment, hygiene and communication among health-care professionals, and knowledge and operational processes. These areas of patient safety have been considered as crucial in previous literature reviews or qualitative analyses, also providing further evidence for the face validity of the proposed PPAEAT questionnaire [18, 23, 24]. Furthermore, this questionnaire was robust against effects of the mental health status. The results support the reliability and validity of this PPAEAT questionnaire with good psychometric properties with regard to the internal consistency, item-scale convergent and item-scale discriminant associations, and concurrent validity.

### Interpretation within the context of the wider literature and implication

This study bridges the research gap regarding the lack of patient involvement, especially concerning their mental health status and their perceptions about patient safety, hence being an important

**Table 2** Item statistics and frequency distributions (N = 210)

Scale/ Item	Mean	SD	Response values frequency			
			1	2	3	4
Scale 1 = Information and communication with patients (M = 2.20; SD = 0.85)						
IC1	2.22	0.80	39	95	66	10
IC2	2.23	0.98	61	60	68	21
IC3	2.06	0.81	57	89	58	6
IC4	2.29	0.79	31	99	68	12
Scale 2 = Time constraints (M = 2.77; SD = 0.73)						
TC1	3.05	0.90	14	38	81	77
TC2	2.97	0.91	17	39	88	66
TC3	2.74	0.94	25	52	86	47
TC4	2.52	0.89	30	68	85	27
TC5	2.56	0.90	32	56	95	27
Scale 3 = Diagnosis and treatment (M = 1.85; SD = 0.92)						
DT1	1.79	0.90	111	63	23	13
DT2	1.83	0.93	99	59	40	12
DT3	1.95	0.92	85	59	57	9
DT4	1.83	0.92	96	65	37	12
Scale 4 = Hygiene and communication among health-care professionals (M = 2.30; SD = 0.91)						
HC1	2.10	0.96	66	79	44	21
HC2	2.33	0.92	45	72	72	21
HC3	2.47	0.85	28	76	85	21
Scale 5 = Knowledge and operational procedures (M = 1.79; SD = 0.65)						
KP1	1.87	0.85	84	78	40	8
KP2	1.80	0.81	86	89	27	8
KP3	1.89	0.77	71	94	42	3
KP4	1.64	0.80	113	65	27	5

Abbreviations: IC = Information and communication with patients, TC = Time constraints, DT = Diagnosis and treatment, HC = Hygiene and communication among health-care professionals, KP = Knowledge and operational procedures. Response values on a 4-point Likert scale. 1='completely disagree', 2='somewhat disagree', 3='somewhat agree' and 4='completely agree'.

contribution to the fields of health-care services research and clinical psychology. It has been shown that patients are able to provide good insights on adverse care processes that potentially endanger patient safety [25]. Potential risks might be preventable by providing health-care professionals with the necessary information on how to reduce triggers [10, 25]. Therefore, from a practical viewpoint, it is important to evaluate indicators of patient safety from the patient perspective as they can help to ensure quality standards in hospitals [26]. Additionally, the results contribute to the understanding of patient-centered care, which is addressing patients with regard to their personal context and needs. As a consequence, patient-centered care is associated with improved adherence and self-care [27]. In that light, a lack of attention and explanation given by health-care professionals may negatively impact patients' assessment of clinicians' knowledge and communicative behavior as well as operational procedures [27].

This PPAEAT questionnaire proves to be generic for the assessment of perceived pAEs, as individual perceptions of triggers do not differ with regard to the mental health status. The only factor associated with perceived patient safety was age. Participants below the age of 50 years perceived lower threats to their safety than those above. This is in line with literature stating that around the age of 50 years, the importance and awareness of preventative medical examinations

**Table 3** Correlation matrix showing the relationship of each item to its subscale corrected for overlap and to the other subscale (N = 210)

Scale/ Item	Scales				
	1	2	3	4	5
Scale 1 = Information and communication with patients (M = 2.20; SD = 0.85)					
IC1	0.72**	0.29	0.46	0.44	0.53
IC2	0.64**	0.32	0.47	0.48	0.47
IC3	0.68*	0.35	0.47	0.42	0.55
IC4	0.70*	0.45	0.45	0.46	0.52
Scale 2 = Time constraints (M = 2.77; SD = 0.73)					
TC1	0.26	0.76**	0.14	0.28	0.23
TC2	0.27	0.66**	0.14	0.21	0.17
TC3	0.32	0.70**	0.25	0.34	0.26
TC4	0.53	0.69**	0.33	0.38	0.39
TC5	0.32	0.63**	0.23	0.46	0.31
Scale 3 = Diagnosis and treatment (M = 1.85; SD = 0.92)					
DT1	0.47	0.15	0.78**	0.31	0.37
DT2	0.47	0.25	0.75**	0.38	0.40
DT3	0.51	0.27	0.70**	0.37	0.32
DT4	0.47	0.26	0.73**	0.36	0.50
Scale 4 = Hygiene and communication among health-care professionals (M = 2.30; SD = 0.91)					
HC1	0.46	0.17	0.32	0.57*	0.42
HC2	0.40	0.46	0.36	0.61**	0.42
HC3	0.49	0.40	0.33	0.58*	0.46
Scale 5 = Knowledge and operational procedures (M = 1.79; SD = 0.65)					
KP1	0.47	0.35	0.40	0.39	0.70**
KP2	0.54	0.23	0.30	0.38	0.61*
KP3	0.47	0.34	0.37	0.54	0.63*
KP4	0.51	0.16	0.43	0.39	0.59*

Note: All correlations were statistically significant (P < 0.05). Two or more than two standard errors were used as a significance level for comparing each item-subscale with its subscale and competing subscale.

\*\*Item-subscale correlation was significantly higher for the associated subscale than for the competing subscale at P < 0.01;

\*Item-subscale correlation was significantly higher for the associated subscale than for the competing subscale at P < 0.05.

**Table 4** Scale internal consistency reliability (N = 210)

Scale	IC	TC	DT	HC	PK
IC	(0.84)				
TC	0.42	(0.78)			
DT	0.56	0.27	(0.88)		
HC	0.55	0.41	0.41	(0.75)	
KP	0.62	0.34	0.47	0.53	(0.81)

Note: Scale internal consistency reliability (Cronbach's alpha coefficient) is presented in the diagonal. IC = Information and communication, TC = Time constraints, DT = Diagnosis and treatment, HC = Hygiene and communication, KP = Knowledge and Procedures.

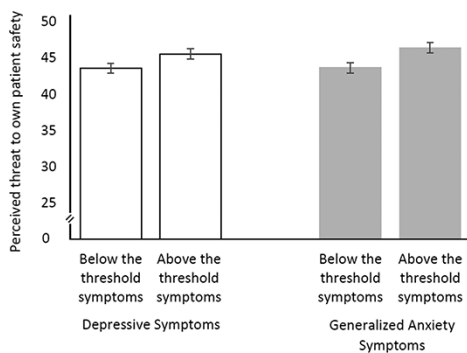
All correlations between scales represented non-diagonally are statistically significant.

P < 0.01.

rise due to a higher need for preventive examination [28]. Higher awareness for prevention may lead to a heightened awareness for patient safety threats as well. However, the exact link between age



Perceived threat to patient safety is expressed as mean scores. Error bars represent standard errors.



**Figure 1** Perceived threat to own patient safety by the mental health status of patients. Perceived threat to patient safety is expressed as mean scores. Error bars represent standard errors.

and awareness for triggers concerning pAEs needs to be investigated in the future.

As previously developed or applied measures in health-care settings frequently only assess patient experience or satisfaction with care [29] and may not provide additional information on the basis of system-level factors that may be interrelated with patient safety [30], the current PPAEAT questionnaire provides a generic tool for clinical practices to routinely evaluate patient safety with regard to quality management aspects and system-level factors relevant for patient safety.

## Limitations

Possible limitations of this study include that this PPAEAT questionnaire was specifically designed to assess perceived triggers of pAEs in hospital settings limiting the generalizability to other health-care settings such as general practices or rehabilitation centers. Future research should, therefore, evaluate this questionnaire not only in clinical hospital settings, but also in medical surgeries and other health-care-related areas. Furthermore, we need to be cautious in the interpretation of the concurrent validity, as we did not compare the newly developed questionnaire to an already existing and well-established assessment tool. Furthermore, developing a short version of this 20-item questionnaire would increase the response rate from patients in health-care settings. Since the questionnaire was evaluated with an online sample, the replication of these results in an offline setting is warranted. Moreover, the current perspective was only examined from the patient perspective; thus, the accompanying persons' viewpoint should be accounted for in future studies. The health-care professionals' perspective could also be added in a dyadic fashion.

## Conclusion

Overall, this study provides support for a generic, reliable and valid tool that measures perceived triggers associated with patient safety in health-care settings, irrespective of gender, last admission as a patient or mental health status. Further research should be undertaken to understand application possibilities in different health-care settings and limitations of the Perceptions of Preventable Adverse

Events Assessment Tool (PPAEAT). The results of this study need to be considered when assessing patient safety, e.g. by using the presented PPAEAT questionnaire, and in the context of health-care research.

## Supplementary material

Supplementary material is available at *International Journal for Quality in Health Care* online.

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## Authors' contribution

F.M.K., C.D., L.K., M.S. and S.L. have contributed to the development of this paper. F.M.K., C.D. and L.K. are research students supervised by S.L.; F.M.K. wrote the first and final draft of this paper. C.D., L.K. and S.L. have contributed to the conception and design as well as the drafting process, and M.S. contributed to the discussion. All authors have read and approved the final manuscript.

## Ethics and other permission

Approval was granted as part of the research project ethical approval from the Ethics Committee at Jacobs University Bremen. All study participants provided written informed consent for participation (ClinicalTrials.gov Identifier: NCT03855735).

## Data availability statement

The data underlying this article will be shared on reasonable request to the corresponding author.

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