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Faculteit Geneeskunde en Levenswetenschappen

master in systeem-en procesinnovatie in de
gezondheidszorg

Masterthesis

From translation to validation: a psychometric validation of the hospital survey on patient safety culture 2.0 (HSOPSC 2.0) and the health information technology (HIT) item list in Dutch for Belgian hospitals: a cross-sectional study

Lotte Geens

Scriptie ingediend tot het behalen van de graad van master in systeem-en procesinnovatie in de gezondheidszorg

PROMOTOR :

Prof. dr. Ward SCHROOTEN



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Adaptation and Psychometric Validation of the HSOPSC 2.0 + HIT supplemental item list in Dutch for Flemish Hospitals: A Cross-Sectional study

Abstract

Introduction

Patient safety culture is essential in healthcare, focusing on preventing harm to patients during care delivery. The Hospital Survey on Patient Safety Culture from the AHRQ has been used in Flemish hospitals since 2007. Since 2019 the HSOPSC 2.0, an updated version has been published. This study validates the Dutch-translated Hospital Survey on Patient Safety Culture (HSOPSC) 2.0 and the supplemental Health Information Technology (HIT) item set to measure the impact of health IT on patient safety culture in Flemish acute hospitals.

Methods

The study comprised two phases: translation and cultural adaptation, followed by a cross-sectional validation study. The HSOPSC 2.0 and HIT item set were translated into Dutch using automated tools and expert reviews. The validation phase involved administering the surveys to staff in three Flemish hospitals, assessing internal consistency and construct validity through Cronbach's alpha, exploratory factor analysis (EFA), and confirmatory factor analysis (CFA).

Results

A total of 2.617 participants completed the HSOPSC 2.0 survey, with 1.907 valid responses analyzed. Cronbach's alpha values ranged from 0.64 to 0.89. EFA confirmed the theoretical constructs of HSOPSC 2.0, with minor discrepancies. CFA indicated a good model fit with SRMSR values below 0.08 and CFI and TLI values around 0.9. The HIT item set, completed by 881 respondents, demonstrated reliable internal consistency and confirmed theoretical dimensions through EFA and CFA.

Discussion

The study validated the Dutch translations of the HSOPSC 2.0 and HIT item set, revealing strong internal consistency and construct validity. Limitations of this study consist of non-response bias and the dominance of nurse respondents.

Conclusion

The Dutch-translated HSOPSC 2.0 and HIT item set are reliable and valid tools for assessing patient safety culture and the impact of health IT in Flemish hospitals. This study supports their use for continuous monitoring and improvement of patient safety culture, contributing to enhanced healthcare quality in Belgium.

Introduction

Patient Safety is a fundamental principle of healthcare. Ensuring that patients are not harmed by the care intended to help them is a critical aspect of healthcare delivery. This involves preventing errors and creating systems and processes that promote a safety culture [1]. In high-income countries, one out of every ten patients experiences harm due to insufficient patient safety measures, resulting in a global loss of 64 million disability-adjusted life years annually. [2]. A lack of patient safety is estimated to be the 14th leading cause of the global disease burden. Patient harm imposes a financial burden, consuming an estimated 15% of hospital expenditures for treatment. [3].

Building a culture of safety within healthcare organizations involves multiple facets, including leadership commitment, staff training, effective communication, and robust systems for reporting and analyzing adverse events. The Institute of Medicine's report "To Err is Human" emphasizes the necessity of systematic changes to reduce medical errors and underscores the safety culture's role in achieving this goal. [4]. The Agency for Healthcare Research and Quality (AHRQ) defines patient safety culture as "the extent to which an organization's culture supports and promotes patient safety." It refers to the values, beliefs, and norms shared by healthcare practitioners and other staff throughout the organization that influence their actions and behaviors [5]. Despite global efforts to reduce the burden of patient harm, significant progress has not been achieved in the past 15 years [2].

Health Information Technology (HIT) plays a significant role in enhancing patient safety. HIT systems, such as electronic health records and clinical decision support systems, help prevent errors by providing timely and accurate information to healthcare providers [6]. Despite these advancements, challenges accompany the implementation and usage of HIT. Organizations must address issues such as resilience, system usability, interoperability and user-friendliness to ensure that HIT positively contributes to patient safety [6][7].

To lower patient harm, the World Health Organization (WHO) has called on countries to create a safety culture in their healthcare systems, leading to the development of the Global Patient Safety Action Plan for 2021-2030. This plan includes actions for healthcare facilities to conduct regular surveys of the organization's safety culture. Governments are urged to enhance coordination and data-sharing mechanisms among various sources of patient safety information [2].

In 2004, the AHRQ published the Hospital Survey on Patient Safety Culture (HSOPSC). Since its publication, hundreds of international hospitals have incorporated this survey into their patient safety strategies [8]. This enables comprehensive data collection worldwide for benchmarking. Given the dynamic nature of healthcare systems and extensive research on patient safety, the AHRQ has published an updated version of this questionnaire – the HSOPSC 2.0. While the new version evaluates many of the same aspects of patient safety culture as the HSOPSC 1.0, various stakeholders have provided feedback over the years, leading to the introduction of modifications [9].

The AHRQ also designed supplemental item sets which can be added to the main HSOPSC 2.0 survey to create a customized HSOPSC. One of these item sets, the Health IT Patient Safety set for Hospital SOPS, helps hospitals assess how their organization's culture responds to the impact of health IT on patient safety from the perspectives of providers and other staff. [10]

The HSOPSC 2.0 contains 40 survey items. Thirty-two survey items make up 10 composite measures: 'Teamwork', 'Staffing and Work Pace', 'Organizational learning', 'Response to Error', 'Supervisor manager or clinical leader support for patient safety', 'Communication about Error', 'Communication Openness', 'Reporting patient safety events', 'Hospital Management Support for Patient Safety', and 'Handoffs and Information Exchange'. There are three additional measures: 'number of events reported', 'patient safety rating', and 'background questions'. In comparison to the HSOPSC 1.0, 21 items were dropped, 25 items were reworded or answer options were changed. 10 new items were added in the latest version of the questionnaire [8].

In 2007, the federal government of Belgium initiated a five-year quality and safety program running from 2007 until 2012. This program required hospitals to regularly measure their safety culture. Hospitals used tools provided by Hasselt University and Ziekenhuis Oost-Limburg for these

measurements. Since then, ongoing data collection from the HSOPSC 1.0 questionnaire has allowed continuous benchmarking of patient safety culture. [11].

With the publication of the newest Hospital Survey on Patient Safety Culture; there is interest in switching to the latest version to continue patient safety culture benchmarking. Additionally, the extensive use of health information technology has led some hospitals to express interest in using the supplemental HIT item list. This allows the measurement of newly developed dimensions, giving hospitals new insights into their patient safety culture. To date, no Dutch translation and cultural adaptation of the HSOPSC 2.0 and the HIT supplemental item list have been undertaken. This research aims to translate and adapt the HSOPSC 2.0 and the supplemental HIT item set into Dutch for implementation in Belgian acute hospitals and to validate this survey psychometrically. The primary research question is: Is the translated and culturally adapted HSOPSC 2.0 and HIT survey psychometrically valid?

Methods

Study design

This study was designed as a two-phase study. The initial phase was performed to translate and culturally adapt the HSOPSC 2.0 and the supplemental HIT item set from English to Dutch. Phase two was a cross-sectional observational study, aimed at validating the psychometric properties of the translated questionnaires within the Flemish healthcare context. This study is reported according to the STROBE guidelines [12].

Phase one: translation and cultural adaptation

The original English version of the HSOPSC 2.0 and the supplemental HIT item list were obtained from the AHRQ website [8][10]. These documents were translated using three automated translation tools: Google translate, ChatGPT and DeepL. Following this step, three bilingual researchers (English-Dutch) independently assessed each translation for accuracy and cultural relevance. Following a comparative analysis and discussion, consensus was reached on the most suitable translations for both surveys. Adjustments were then made to reflect job functions and workplace contexts within the Belgian setting. A draft of both surveys was sent out to five field experts for review and to ensure the translation and adaptation. Their feedback was considered and implemented by designing the final Dutch version of the HSOPSC 2.0 (Append table 1) and the supplemental HIT item set (Append table 2). The final versions were programmed into Qualtrics [13] – an online survey tool. A formal content validity assessment was not conducted.

Phase two: Cross-sectional validation study

Setting

The validation phase was conducted in three hospitals in Flanders, selected based on their willingness to participate. These hospitals comprised one academic hospital and two general hospitals. The academic and one of the general hospitals included the HIT supplemental item list. Data was collected through the online Qualtrics survey from February 1st until March 31st. One primary contact person was designated per hospital, responsible for disseminating the survey link to the potential participants.

Participants

Hospitals previously engaged with the HSOPSC 1.0 benchmark were invited to participate in this study. Three hospitals agreed to participate in the cross-sectional study, although one general hospital opted out of using the HIT supplemental item list. Eligibility for participation in the HSOPSC 2.0 survey was extended to all employees active at these hospitals with no additional participation criteria. Only those employees actively working with an electronic health record (EHR) were eligible for the HIT supplemental item list survey. The survey included an option for participants to indicate their interaction with EHR; those responding negatively automatically skipped the supplemental items. Participants received the Qualtrics survey link by email, sent by the hospital's primary contact person.

Variables

The primary outcomes focused on the psychometric properties of the Dutch-translated HSOPSC 2.0 and the HIT item list, including internal consistency (assessed by Cronbach's alpha) and construct validity (evaluated through exploratory and confirmatory factor analyses). The positive response rate per domain was calculated and the distribution of responses was visualized by a heatmap.

Potential confounders might have influenced the relationship between the exposure and the outcome. The type or size of the hospital, as well as the language proficiency among respondents, could affect their understanding and responses to the survey items. In the HIT supplemental item list, the software used as the EHR might impact healthcare worker's opinions. No quantitative analysis of confounders was performed in this research.

Data sources / Measurements

The HSOPSC 2.0 includes 40 items, 32 of which were grouped into 10 dimensions that define the concept of "patient safety culture". These items were scored on a five-point Likert Scale for agreement ranging from 'strongly disagree' to 'strongly agree' or a frequency scale from 'never' to 'always'. An additional response option 'does not apply or don't know' was also provided. Three further measures in the questionnaire include the number of events reported, patient safety rating, and background questions.

The HIT supplemental item set comprised 15 items covering five topic areas (Append table 2). Nine items used a five-point Likert Scale from strongly disagree to strongly agree, five items were scored on a frequency scale from none to more than 50 times. One item measured the overall EHR system rating on a scale from very dissatisfied to very satisfied.

Bias

To mitigate potential biases, several strategies were employed. Diverse hospital settings aimed to reduce the impact of site-specific biases. Anonymity in survey participation was ensured to help limit response bias. The translation process included multiple stages of review and consensus to minimize language related errors and biases.

Study size

The estimated sample size was calculated to include 15 to 20 respondents per item [14], suggesting an initial sample size of 600 to 800 respondents for the HSOPSC 2.0 and 225 to 300 for the HIT supplemental item list. There was a response rate of approximately 60% anticipated. An adjusted sample size was calculated to meet the upper end of the item-to-respondent ratio, requiring to reach at least 1334 respondents for the HSOPSC 2.0 and 500 respondents for the HIT supplemental item list.

Quantitative variables

The 32 items of the HSOPSC 2.0 making up the 10 dimensions were treated as quantitative variables with responses captured on a five-point Likert Scale. The 15 items of the HIT supplemental list were also treated as quantitative variables including both Likert and frequency scales. Dimension scores were derived from the ratio of positive responses to the total. Responses to negatively worded questions were re-coded to align positively for analysis consistency.

Statistical Methods

Descriptive statistics summarized the survey responses, response rates, response symmetry and the positive percentage per dimension. To calculate the mean and positive percentages per dimension, answers with 'doesn't apply / I don't know' were left out [8]. According to the guidelines of the AHRQ only 100% completed surveys were included in the analysis [8][10]. The internal consistency of the HSOPSC 2.0 and HIT dimensions was evaluated using Cronbach's alpha, with a benchmark of 0.7 or higher for acceptable consistency [15]. This was used to underscore the reliability of the dimensions as set in the original English version of the HSOPSC 2.0 and HIT. Further analyses included an Exploratory factor analysis (EFA) to investigate the latent structure of survey items without a predetermined number of factors [16], revealing natural groupings based on participant perceptions

of patient safety culture. A Confirmatory factor analysis (CFA) validated the emergent factor structure against the theoretical construct of the HSOPSC 2.0 and HIT supplemental item list, employing fit indices such as the Standardized Root Mean Square Error of Approximation, Comparative Fit Index and the Tucker-Lewis index to gauge model accuracy [17]. This was done to validate the dimensional construct of the surveys within the Belgian healthcare context. All statistical analyses were conducted using R studio version 2023.12.1+402 [18].

Results

The panel of field experts recommended alterations for the first and second questions concerning the participant's job position and work area. Some job positions identified by field experts were not present in the hospitals they were affiliated with, some positions and work areas were not listed in the questionnaire. These recommendations were reviewed and appropriate modifications were made to align the questions and answer options with the Belgian context. Certain sentences were rephrased for more clarity and some words underwent alternative translations. For the English word Error there is no direct Dutch translation, therefore it was translated into Dutch as the equivalent of 'almost incidents'. Append table 1 and Append table 2 display the translations of the dimensions and corresponding items of the HSOPSC 2.0 and the supplemental HIT item set, respectively.

Results HSOPSC 2.0

Participant Characteristics

A total of 2.617 healthcare professionals and hospital staff participated in the HSOPSC 2.0. Of these 27 opted out and 683 were excluded from the final analysis due to incomplete questionnaires, resulting in 1.907 fully completed responses. As detailed in Append table 3, the distribution of professional roles among the respondents was diverse, with nurses representing approximately 45% of the participants, thereby representing the largest professional group.

Regarding tenure, half of the respondents reported being employed in the hospital for 11 years or more, and 40% indicated they had worked in their current specific work area for the same duration. A large portion of the workforce, 67%, reported working between 30 to 40 hours per week. Additionally, 77% confirmed having direct patient contact in their daily roles.

Descriptive Item analysis

Analysis of survey items indicated minimal skewness across responses, confirming an acceptable level of response symmetry as presented in Figure 1. Notably, no survey item received more than 50% of responses at any one point on the six-point Likert Scale, with the exception of question D3.

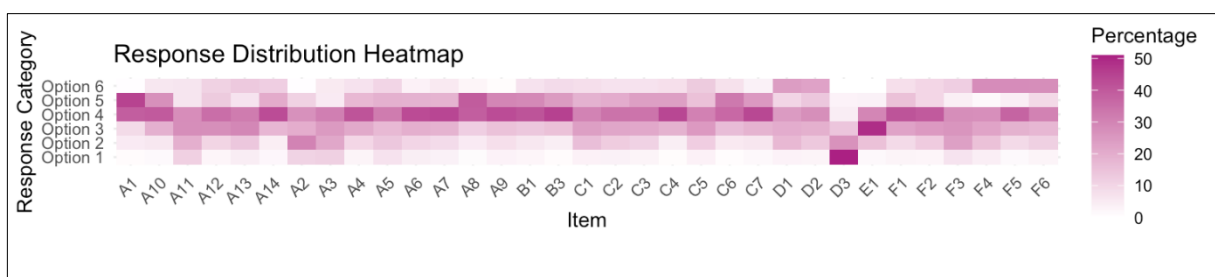


Figure 1 Response Distribution Heatmap HSOPSC 2.0

Table 1 shows the descriptive statistics for the HSOPSC 2.0 with means per dimension ranging from 3.11 to 4.08 on a five-point Likert Scale where 5 means 'Strongly Agree' and 1 indicates 'Strongly Disagree'. The percentage of positive responses ranges from 79% on the dimension Teamwork to the lowest of 43% on the dimension Staffing and Work Pace.

Table 1 Descriptive Statistics for the HSOPSC 2.0

Subscale (Number of items)	M (SD)	Cronbach's Alpha		Percentage of Positive Responses	
		This study	Original HSOPSC 2.0	This study (%)	Original Pilot HSOPSC 2.0 (%)
Teamwork (3)	4.08 (0.96)	0.69	0.76	79	81
Staffing and Work Pace (3)	3.11 (1.18)	0.73	0.67	43	56
Organizational learning - Continuous Improvement (3)	3.64 (0.98)	0.73	0.76	62	72
Response to Error (4)	3.64 (1.03)	0.74	0.83	61	61
Supervisor, Manager, or clinical Leader Support for Patient Safety (3)	3.88 (0.95)	0.78	0.77	73	81
Communication about Error (3)	3.59 (1.10)	0.88	0.89	58	68
Communication Openness (4)	3.85 (0.97)	0.80	0.83	68	76
Reporting Patient Safety Events (2)	3.39 (1.09)	0.89	0.75	50	74
Hospital Management Support for Patient Safety Handoffs and Information Exchange (3)	3.37 (1.03)	0.82	0.77	51	68
	3.33 (0.98)	0.86	0.72	51	58

Reliability analysis

The internal consistency of the survey's ten dimensions was assessed using Cronbach's Alpha, with results summarized in Append table 4. The coefficients ranged from 0.69 to 0.89. Nine dimensions exhibited coefficients above 0.7, whereas one dimension fell below this threshold at 0.69. The overall internal consistency was comparable to that observed in both the original survey and its Dutch translation. The removal of items A13, B2, and F3 was found to potentially enhance the Cronbach's Alpha for their respective dimensions.

Exploratory factor analysis (EFA)

The EFA as shown in **Fout! Verwijzingsbron niet gevonden.** was based on a hypothesized structure of ten dimensions, intended to measure latent constructs across 32 items. The analysis identified ten dimensions with corresponding items that demonstrated the highest factor loadings. The EFA results aligned with the theoretical constructs in seven out of ten evaluated dimensions. However, discrepancies were observed for four items (A4, A13, C6, and C4) which did not align as anticipated with the theoretical model.

Confirmatory factor analysis (CFA)

The CFA evaluated the fit of the empirical data to the hypothesized dimensional structure. The fit indices reported in Table 2 suggest nuanced interpretations of model adequacy. The Chi-square test statistic was 2652.416 with 419 degrees of freedom, leading to a p-value of less than 0.000, indicating a statistically significant discrepancy between the hypothesized model and the observed data. The Standardized Root Mean Square Residual (SRMSR) was approximately 0.053, suggesting an acceptable fit. Both the Comparative Fit Index (CFI) and the Tucker-Lewis Index (TLI) approached 0.9.

Table 2: Confirmatory Factor Analysis HSOPSC 2.0

Goodness of fit statistics	Estimates
Chi square	2652.416
Chi square DF	419
P-value (Chi-square)	< 0.000
Standardized RMSR	0.053
Comparative Fit Index (CFI)	0.919
Tucker-Lewis Index (TLI)	0.9

Results HIT supplemental item list

Participant Characteristics

The HIT survey was a supplemental item list added to the original HSOPSC 2.0 survey. Eligibility for the HIT survey required participants to affirmatively answer the question: 'Do you use your Hospital's Electronic Health Record System to enter or review patient information?' Of the 1,227 participants who responded to this question, 246 left it unanswered and 881 participants affirmed, which qualified them to complete the HIT supplemental item list. As shown in Append table 5, participants represented all possible staff positions except for security. Over half (51%) had been working 11 years or longer in the hospital and 42% worked 11 years or longer in the same work area. 67% of the participants worked between 30 to 40 hours per week and 88% reported regular direct contact with patients.

Descriptive Item Analysis

The Descriptive Item Analysis of the HIT survey showed no extraordinary distribution towards any answer option, with the highest percentage on one answer option being 60%. As shown in Figure 2, item A4 and A5 scored high on the first answer option going up to 60%.

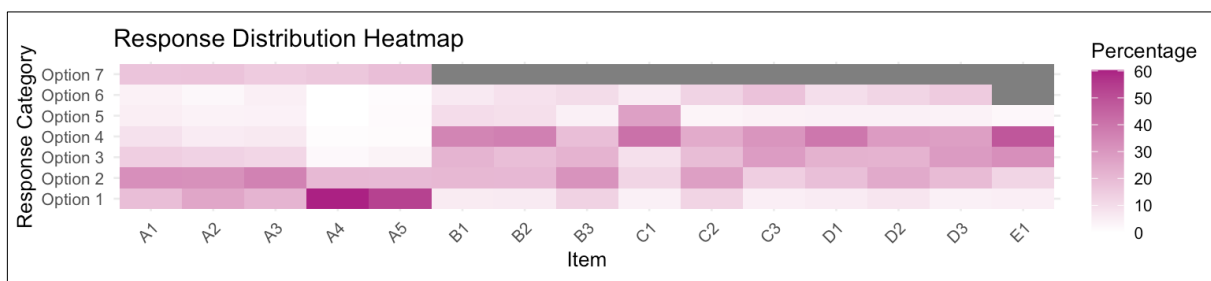


Figure 2: Response Distribution Heatmap HIT

Table 3 shows the descriptive statistics for the supplemental HIT item list with means ranging from 2.85 to 3.59. For the Dimension 'EHR Patient Safety and Quality Issues' scores were measured on a frequency rating scale going from 1 = None and 6 = More than 50 times. Dimensions 'EHR System Training', 'EHR Workflow/ Work Process' and 'EHR System Support and Communication' were measured on a five-point Likert Scale for Agreement where 1 = Strongly Disagree and 5 = Strongly agree. The overall EHR System rating was also measured on a five-point Likert Scale for Satisfaction where 1 = Very Dissatisfied and 5 = Very Satisfied. The Percentages of Positive Responses ranged from 41% to 50% where two subscales had a higher percentage of positive responses than the original pilot study of the HIT supplemental item list.

Table 3: Descriptive Statistics for the HIT

Subscale (Number of items)	M (SD)	Cronbach's Alpha	Percentage of Positive Responses	
		This study	This study (%)	Original Pilot HIT (%)
EHR Patient Safety and Quality Issues (5)	2.85 (2.19)	0.92	/	/
EHR System Training (3)	3.30 (1.36)	0.79	41	64
EHR and Workflow/ Work Process (3)	3.59 (1.41)	0.64	49	42
EHR System Support and Communication (3)	3.45 (1.36)	0.78	41	50
Overall EHR System rating (1)	3.31 (0.89)	/	50	45

Reliability analysis

The Health Information Technology survey, which assessed various dimensions of the EHR system's impact on patient safety culture, produced the following Cronbach's alpha values (Append table 6): Dimension 1 achieved an alpha of 0.79, Dimension 2 an alpha of 0.78, Dimension 3 exhibited the highest alpha at 0.92, and Dimension 4 the lowest at 0.64. Upon analysis of item deletion, the first three dimensions displayed minimal variation in alpha values. In contrast, Dimension 4 showed greater variability: deletion of item C1 increased the alpha to 0.74, whereas removal of items C2 and C3 reduced it to 0.35 and 0.43, respectively.

Exploratory Factor Analysis

The EFA identified four factors based on eigenvalues and a parallel analysis. As shown in Append figure 2, the first identified factor comprised items A1 through A5 showing factor loadings ranging from 0.79 to 0.9. The second factor identified included items B1 to B3 and showed loadings from 0.58 to 0.78. Items C1 to C3 loaded on the third factor having the highest loadings at 0.74 and 0.71. Factor 4 involved items D1 to D3 with a factor loading ranging from 0.4 to 0.7. The sum of squared loadings for the factors explained a cumulative 60% of the variance.

Confirmatory factor analysis

The CFA aimed to validate the structural integrity of the identified factors; the Chi-square statistic was 721.984 with 71 degrees of freedom resulting in a p-value of < 0.00. The standardized root mean square residual was 0.058 which is below the typical threshold of 0.08. The comparative fit index and the Tucker-Lewis Index respectively were 0.9 and 0.87 (Table 4)

Table 4: Confirmatory Factor Analysis HIT

Goodness of fit statistics	Estimates
Chi square	721.984
Chi square DF	71
P-value (Chi-square)	< 0.000
Standardized RMSR	0.058
Comparative Fit Index (CFI)	0.9
Tucker-Lewis Index (TLI)	0.9

Discussion

Key Results

Correspondents and characteristics

The HSOPSC 2.0 and HIT surveys represent important steps in understanding and evaluating patient safety in hospital settings. With an initial engagement of 2,617 participants for the HSOPSC 2.0 and 1,907 complete responses, the surveys underscore interest in patient safety among healthcare professionals. This response rate emphasizes the importance of safety cultures in healthcare, particularly noted by the substantial representation of nurses, who make up approximately 45% of respondents. Considering that nurses constitute the majority of hospital staff, their role is pivotal. They frequently interact directly with systems that impact patient safety, thus providing essential insights into the operational aspects of safety culture. This makes their input invaluable for understanding and improving the conditions that affect patient safety culture. [19]. The demographic and tenure information collected suggests that the insights provided by respondents are based on rich, experienced backgrounds, with many participants having over a decade of service. This depth of experience is critical in providing informed responses that reflect long-term observations and interactions with the institutional safety cultures, rather than transient or superficial assessments.

Reliability analysis

The strong internal consistency indicated by the Cronbach's Alpha values, ranging from 0.64 to 0.89 across various dimensions of the survey, demonstrates that the survey instruments are reliable and robust in measuring the intended constructs. Two dimensions did not meet the minimum value for acceptable reliability, which is set at a Cronbach's Alpha of 0.70 [15]. In the HSOPSC 2.0 survey, the 'Teamwork' dimension recorded an alpha of 0.69, slightly below the threshold and lower than the original instrument's alpha of 0.76. Despite exploring the potential improvement by dropping an item, the alpha value did not increase to 0.70 or above.

Similarly, in the HIT survey, the 'EHR and Workflow/Work Process' dimension exhibited a lower reliability with an alpha of 0.64. Notably, the original instrument does not recognize this cluster of items as a separate dimension. However, if item C1—which queries whether sufficient computers with access to the EHR are available when needed—was removed, the Alpha would increase to 0.74, surpassing the acceptable threshold. This suggests that item C1 may not align well with the other items in this dimension, impacting the overall reliability measure.

Exploratory factor analysis

The EFA for the HSOPSC 2.0 largely confirmed the theoretical constructs with seven out of ten dimensions aligning as expected. Items A13, A4, C6 and C4 were misaligned.

Item A4, theoretically associated with 'Organizational Learning and Continuous Improvement' was grouped under 'Supervisor, Manager, or clinical leader Support for Patient Safety' with a factor loading of 0.4 compared to the factor loading of 0.3 with its theoretical dimension.

Item C4 which was theoretically associated with Communication Openness was grouped under Communication about error. The EFA dimension had a factor loading of 0.4 compared to the factor loading of 0.38 with its theoretical dimension.

Item C6 was also placed in different dimensions than initially predicted, being placed under the dimension 'Supervisor, Manager, or clinical leader Support for Patient Safety' with a factor loading of 0.5 compared to its theoretical dimension 'Communication Openness' where the item had a factor loading of 0.46.

Lastly, item A13 was theoretically placed with the dimension 'Communication about error' where it had a factor loading of 0.13 but according to the EFA it should be placed with 'Organizational learning – Continuous Improvement' where it had a factor loading of 0.6.

The difference between factor loadings of the theoretical dimension and the EFA dimension for items C4 and C6 were minor. The difference between the factor loadings for items A4 and A13 were larger indicating that the item might have a better fit in another dimension. Though the dimensions that

these items are under have a rather high Cronbach Alpha and dropping one of these items in the theoretical dimension would lower the Cronbach Alpha of that dimension.

For the HIT survey, the EFA confirmed the theoretical constructs with a clear alignment of items under identified dimensions, reinforcing the survey's design.

Confirmatory factor analysis

The CFA offered a nuanced but instructive perspective on the model's fit. The chi-square test revealed a significant discrepancy, illustrating a well-documented issue in survey-based research involving large samples. Specifically, the chi-square test is known for its sensitivity to sample size, which can lead to minor misalignments being interpreted as statistically significant deviations [20].

Despite the chi-square test results, other fit indices provided a more reassuring assessment of the model's adequacy. The Comparative Fit Index (CFI), which compares the existing model's fit to a baseline model assuming no correlation among factors, indicated a near-adequate fit with values of 0.9 for both surveys, whereas the generally accepted threshold for CFI is 0.95 or above [21]. While a value of 0.9 suggests that the models are reasonably close to representing the data accurately, it is slightly below the ideal.

Furthermore, the Standardized Root Mean Square Residual (SRMSR), which measures the standardized difference between the observed and predicted covariance, showed values of 0.05 for both the HSOPSC 2.0 and HIT surveys. Values less than 0.08 are typically indicative of a good model fit [22], confirming that, on this metric, both surveys demonstrate strong alignment with the underlying data structures.

Additionally, the Tucker Lewis Index (TLI), which also ranges between 0 and 1 with values greater than 0.9 generally indicating a good fit, mirrored the CFI at 0.9 for both surveys. This consistency across multiple indices, despite the chi-square results, suggests that the overall structural models of the HSOPSC 2.0 and HIT surveys are sound and provide a reliable framework for understanding patient safety culture and the impact of health information technology in healthcare settings.

Limitations

The study's methodology encompasses inherent limitations typical for extensive survey research. A primary concern is the dropout and non-completion rate, which introduces non-response bias. This bias occurs when individuals who do not complete the survey differ significantly in their views or characteristics from those who do, potentially skewing results by overrepresenting or underrepresenting certain perspectives or issues in patient safety culture. The magnitude of this bias could be significant, particularly if those who dropped out had systematically different perceptions of patient safety compared to those who completed the survey. Additionally, the dominance of nurse respondents, while providing valuable insights from a frontline care perspective, limits broader insights into the findings that could be gained from a more diverse sample.

Another limitation arises from the commitment to maintaining a consistent survey format for international benchmarking purposes. This restriction hinders modifications to the survey's structure or item composition that might be necessary. While this approach facilitates benchmarking across different countries, it can also introduce bias by forcing a uniform framework that may not completely capture local or specialized issues.

Interpretation

The HSOPSC 2.0 and HIT surveys have provided valuable insights into the psychometrical validity of the surveys. The analysis demonstrates a strong internal consistency across most surveyed dimensions, suggesting that the survey instruments are effectively capturing the intended constructs of patient safety culture. However, the findings from exploratory and confirmatory factor analyses indicate that there are some subtle nuances and some misalignments that must be considered.

Several validation studies of the HSOPSC 2.0 have translated the survey into various languages, showing comparable Cronbach's alpha values to this study. For instance, one study also reported a slightly lower Cronbach's alpha of 0.68 for the teamwork dimension [23]. Cronbach Alpha's of other dimensions were comparable with the Chinese and Turkish validation study [24][25], indicating consistency across language adaptations in capturing the construct of patient safety culture.

The use of the chi-square statistic in CFA presents inherent limitations, notably its sensitivity to large sample sizes, which can exaggerate minor misalignments as statistically significant, no other similar validation studies have been found to report the chi-square statistic. This sensitivity highlights the need for cautious interpretation of these results, considering the multiplicity of analyses and the broader survey objectives. While other fit indices like the CFI, TLI and SRMSR indicate a reasonably good fit, they all fall slightly below the ideal thresholds commonly accepted in survey research. Though the TLI and SRMSR values are comparable with the values measured for the Chinese validation of the HSOPSC 2.0 [24] and for the Turkish version [25]. This suggests that although the survey frameworks are generally robust, there is potential for refining how certain survey items are structured or phrased, especially those that did not align as expected with their theoretical constructs.

Remarkably, this study is pioneering in its validation and analysis of the HIT supplemental item list in other languages, as no comparable results were found in the literature review. This positions the current findings as a good first step in understanding the specific dynamics of Health Information Technology's impact on patient safety.

Generalizability

The generalizability, or external validity, of the study results is supported by the diverse and substantial participation of healthcare professionals in both surveys. However the participant base of this study is heavily skewed towards nurses and may limit the application of findings to other healthcare roles.

The study is conducted in the specific Flemish healthcare and cultural context. As it stands, the Belgian healthcare setting, particularly within the Flemish region has its unique characteristics, which may limit the extent to which results can be directly transferred to other settings. However, the systematic approach to translation, adaptation, and validation of the HSOPSC 2.0 and HIT supplemental item list provides a robust framework that could be emulated in different linguistic and cultural environments.

The international benchmarking aspect of these surveys imposes certain limitations on how much the survey structure can be modified in response to findings from specific contexts. This restriction is crucial for maintaining the ability to compare results across different countries and cultural settings, yet it may limit the sensitivity of the survey to specific cultural or institutional nuances in patient safety culture. Therefore, while the results are broadly applicable across similar healthcare settings, they should be interpreted with consideration of these structural constraints.

Conclusion

This study demonstrates a successful adaptation and validation process, ensuring that the surveys are psychometrically sound and reflect the specific nuances of the Flemish hospitals. It supports the robustness of the HSOPSC 2.0 and HIT survey as tools for monitoring and enhancing patient safety culture.

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Appendix

Appendix A: Table 1

Append table 1: Safety Culture Dimensions and Component items listed in order of appearance in HSOSPC version 2.0

Dimension	Item	Description
1) Teamwerk	A1	In deze afdeling / werkomgeving werken we als een goed functionerend team samen.
	A8	Wanneer het druk is, helpen medewerkers op deze afdeling / werkomgeving elkaar.
	A9 ^R	Op deze afdeling / werkomgeving is er een probleem van respectloos gedrag onder de medewerkers.
2) Personeelsbezetting en werktempo	A2 ^R	In deze afdeling / werkomgeving hebben we voldoende medewerkers om de werklust aan te kunnen.
	A3	In deze afdeling / werkomgeving werken medewerkers/collega's te veel uren om nog optimale zorgverlening te kunnen geven.
	A5 ^R	Deze afdeling / werkomgeving is te veel afhankelijk van mobiele/vlinder/interim medewerkers.
	A11 ^R	Het werktempo op deze afdeling / werkomgeving is zo hoog dat dit een negatieve invloed heeft op de patiëntveiligheid.
3) Organisationeel leren - Continue verbetering	A4	Deze afdeling / werkomgeving beoordeelt regelmatig de werkprocessen om veranderingen ter verbetering van patiëntveiligheid te overwegen.
	A12	Op deze afdeling / werkomgeving worden verbeteracties m.b.t. patiëntveiligheid geëvalueerd en wordt er gekeken of ze effectief tot resultaat hebben geleid.
	A14 ^R	Deze afdeling laat dezelfde problemen omtrent patiëntveiligheid keer op keer gebeuren.
4) Reactie op (bijna-)incidenten	A6 ^R	Op deze afdeling / werkomgeving hebben medewerkers het gevoel dat hun fouten tegen hen worden gebruikt.
	A7 ^R	Wanneer er op deze afdeling / werkomgeving een (bijna-)incident wordt gerapporteerd, voelt het alsof de persoon wordt aangepakt in plaats van het probleem.
	A10	Wanneer (bijna-)incidenten zich voordoen, ligt de focus op het leren uit incidenten in plaats van het beschuldigen van de medewerker.
	A13 ^R	Op deze afdeling / werkomgeving is er onvoldoende ondersteuning voor medewerkers die betrokken zijn bij patiëntveiligheidsincidenten.
5) Ondersteuning van supervisor, diensthoofd of medisch leidinggevende voor patiëntveiligheid	B1	Mijn rechtstreekse supervisor, diensthoofd of medisch leidinggevende neemt suggesties van medewerkers ter verbetering van patiëntveiligheid ernstig in overweging.

	B2 ^R	Mijn rechtstreekse supervisor, diensthoofd of medisch leidinggevende wil dat we sneller werken tijdens drukke tijden, zelfs als we daarvoor stappen in procedures moeten overslaan.
	B3	Mijn rechtstreekse supervisor, diensthoofd of medisch leidinggevende onderneemt actie wanneer er patiëntveiligheidsissues worden opgemerkt.
6) Communicatie over (bijna-)incidenten	C1	We worden geïnformeerd over (bijna-) incidenten die zich op deze afdeling / werkomgeving voordoen.
	C2	Wanneer er op deze afdeling / werkomgeving (bijna-) incidenten optreden, bespreken we hoe we dit kunnen voorkomen in de toekomst.
	C3	Op deze afdeling / werkomgeving worden we geïnformeerd over de verbeteracties die zijn ingevoerd naar aanleiding van incidenten.
7) Openheid in communicatie	C4	Op deze afdeling / werkomgeving spreken medewerkers zich uit als ze iets zien dat de patiëntenzorg negatief kan beïnvloeden.
	C5	Als medewerkers op deze afdeling / werkomgeving zien dat iemand met meer autoriteit iets doet wat onveilig is voor patiënten, kunnen ze hierover vrijuit spreken.
	C6	Wanneer medewerkers op deze afdeling / werkomgeving hun bezorgdheden over patiëntveiligheid uiten, staan hun supervisors / leidinggevendenden hiervoor open.
	C7	Op deze afdeling / werkomgeving zijn de medewerkers bang om vragen te stellen als er iets niet klopt.
8) Melden van patiëntveiligheids incidenten	D1	Er loopt iets mis tijdens het zorgproces, maar dit wordt opgemerkt en gecorrigeerd voor de patiënt er schade van ondervindt (bijna-incident). Hoe vaak wordt dit gemeld?
	D2	Er gebeurt een incident dat de patiënt schade had kunnen berokkenen, maar hem uiteindelijk ongedeerd liet. Hoe vaak wordt dit gemeld?
9) Ondersteuning van het ziekenhuismanagement voor patiëntveiligheid	F1	De acties van het ziekenhuismanagement tonen aan dat de patiëntveiligheid een topprioriteit is
	F2	Het ziekenhuismanagement biedt voldoende middelen om de patiëntveiligheid te verbeteren
	F3 ^R	Het ziekenhuismanagement lijkt pas geïnteresseerd in patiëntveiligheid nadat er een incident heeft plaatsgevonden
10) Overdracht en informatie-uitwisseling	F4 ^R	Bij het overbrengen van patiënten van de ene afdeling naar de andere wordt vaak belangrijke informatie over het hoofd gezien
	F5 ^R	Tijdens dienstwisselingen wordt vaak belangrijke informatie over patiëntenzorg over het hoofd gezien.
	F6	Tijdens dienstwisselingen is er voldoende tijd om alle belangrijke informatie over patiëntenzorg uit te wisselen.

R – Reversed items

Appendix B: Table 2

Append table 2: Safety Culture Dimensions and Component items listed in order of appearance in Health Information Technology Patient Safety Supplemental Item Set for Hospitals

Dimensie	Item	Beschrijving
1) Het elektronisch patiëntendossier (EPD): kwaliteit en patiëntveiligheid	A1	informatie was niet volledig
	A2	informatie was niet accuraat
	A3	Belangrijke informatie was moeilijk te vinden
	A4	Gegevens werden ingevoerd in het verkeerde patiëntendossier
	A5	Er is onjuiste informatie gekopieerd en geplakt
2) Opleiding over het gebruik van het elektronisch patiëntendossier	B1	we krijgen voldoende training over het gebruik van ons EPD
	B2	De training over ons EPD is afgestemd op onze werkomgeving
	B3	We zijn voldoende getraind in wat we moeten doen wanneer het EPD niet beschikbaar is
3) EPD en workflow/werkproces	C1	Er zijn voldoende computers/tablets met toegang tot het EPD beschikbaar wanneer wij deze nodig hebben.
	C2 ^R	Ons EPD vereist dat we dezelfde informatie op te veel plaatsen moeten invoeren.
	C3 ^R	Er zijn te veel waarschuwingen of vlaggen in ons EPD.
4) Ondersteuning en communicatie met betrekking tot het EPD	D1	Problemen met ons EPD worden tijdig opgelost
	D2	Er wordt ons om input gevraagd over manieren om ons EPD te verbeteren
	D3	We worden gewezen op problemen met ons EPD die tot fouten kunnen leiden
5) Algemene beoordeling van het EPD	E1	Hoe tevreden bent u over het EPD van uw ziekenhuis

R – Reversed items

Appendix C: Table 3

Append table 3: Respondent Characteristics HSOPSC 2.0

Respondent Characteristics	Respondents	
Hospital Staff Position	Number	Percent
Verpleegkundig specialist / master verpleegkundige	154	6,1
Bachelor verpleegkundige (HBO6)	616	24,39
Gegradueerd verpleegkundige (HBO5)	362	14,33
Zorgkundige	67	2,65
Arts-assistent in opleiding	9	0,36
Arts	138	5,46
Diëtist	11	0,44
Apotheker	26	1,03
Kinesitherapeut, ergotherapeut, logopedist	87	3,44
Psycholoog	26	1,03
Maatschappelijk werker / sociaal verpleegkundige	19	0,75
Technoloog (EKG, Laboratorium, Radiologie)	91	3,6
(Adjunct-)hoofdverpleegkundige, programmamanager, middenkader, teamleider	155	6,14
Directie	10	0,4
Medewerker technische dienst	38	1,5
Medewerker voeding	39	1,54
Medewerker huishouding / schoonmaak	99	3,92
Medewerker informatietechnologie (IT)	34	1,35
Medewerker beveiliging	5	0,2
Medewerker logistiek, patiënt-/goederentransport	69	2,73
Afdelingsmedewerker, secretaresse, receptionist, kantoormedewerkers	292	11,56
Andere	179	7,09
	Total	2526
	N/A	64
	General total	2590
Tenure in Hospital	Number	Percent
Minder dan 1 jaar	114	5,79
1 tot 5 jaar	535	27,16
6 tot 10 jaar	313	15,89
11 of meer jaren	1008	51,17
	Total	1970
	N/A	620
	General total	2590
Tenure in Unit/ Work Area	Number	Percent

Minder dan 1 jaar	155	7,88
1 tot 5 jaar	687	34,93
6 tot 10 jaar	334	16,98
11 of meer jaren	791	40,21
Total	1967	100
N/A	623	
General total	2590	

Hours Worked per Week in Hospital	Number	Percent
Minder dan 30 uur per week	368	18,71
30 tot 40 uur per week	1316	66,9
Meer dan 40 uur per week	283	14,39
Total	1967	100
N/A	623	
General total	2590	

Interaction With Patients	Number	Percent
JA, ik heb doorgaans direct contact met patiënten	1509	76,68
NEE, ik heb doorgaans GEEN direct contact met patiënten	459	23,32
total	1968	100
N/A	622	
General total	2590	

Appendix D: Table 4

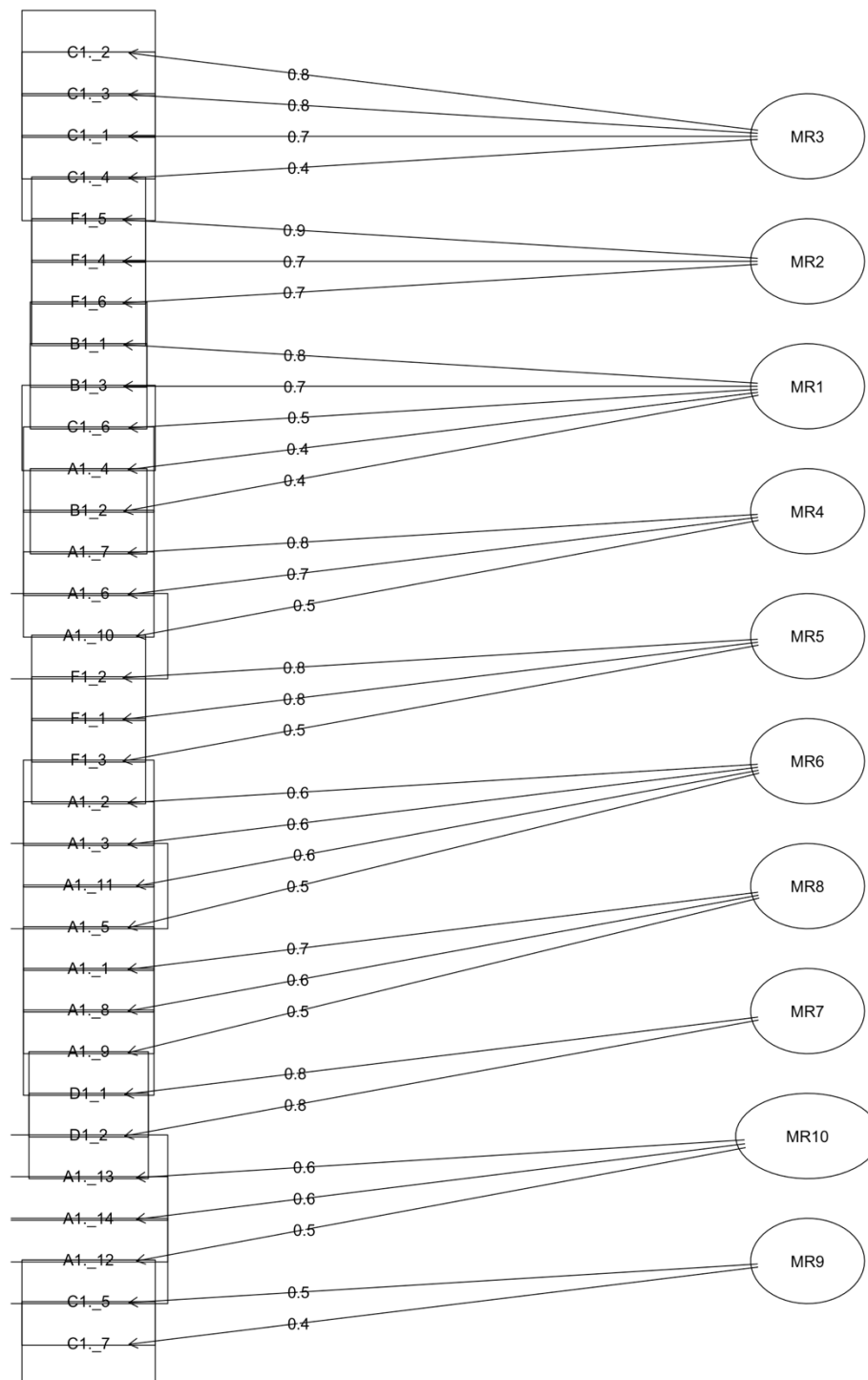
Append table 4: Cronbach Alpha HSOPSC 2.0

Dimension	Item	CI 95%	Cronbach's Alfa if item deleted	Cronbach's Alfa	Cronbach's Alfa original survey
1) Teamwerk		0,68 - 0,70		0,69	0,76
	A1		0,52		
	A8		0,6		
	A9		0,65		
2) Personeelsbezetting en werktempo		0,72 - 0,74		0,73	0,67
	A2		0,69		
	A3		0,65		
	A5		0,68		
	A11		0,64		
3) Organisationeel leren - Continue verbetering		0,72 - 0,75		0,73	0,76
	A4		0,65		
	A12		0,55		
	A14		0,72		
4) Reactie op (bijna-)incidenten		0,73 - 0,75		0,74	0,83
	A6		0,64		
	A7		0,57		
	A10		0,65		
	A13		0,79		
5) Ondersteuning van supervisor, diensthoofd of medisch leidinggevende voor patiëntveiligheid		0,76 - 0,79		0,78	0,77
	B1		0,63		
	B2		0,83		
	B3		0,64		
6) Communicatie over (bijna-)incidenten		0,88 - 0,89		0,88	0,89
	C1		0,86		
	C2		0,81		
	C3		0,84		
7) Openheid in communicatie		0,78 - 0,81		0,8	0,83
	C4		0,75		
	C5		0,72		
	C6		0,71		
	C7		0,79		
8) Melden van patiëntveiligheids incidenten		0,88 - 0,90		0,89	0,75
	D1		0,84		
	D2		0,76		
9) Ondersteuning van het ziekenhuismanagement voor patiëntveiligheid		0,80 - 0,82		0,82	0,77
	F1		0,71		
	F2		0,68		

	F3	0,84		
10) Overdracht en informatie-uitwisseling		0,85 - 0,87	0,86	0,72
	F4	0,82		
	F5	0,74		
	F6	0,83		

Appendix E Figure 1

Factor Analysis



Append figure 1: Exploratory Factor Analysis HSOPSC 2.0

Appendix F table 5

Append table 5: Respondent Characteristics HIT

Respondent Characteristics	Respondents	
Do you use your Hospital's Electronic Health Record (EHR) system to enter or review patient information ?	Respondents	
	Number	Percent
Ja	881	72
Nee	346	28
Total	1227	100
N/A	246	
General total	1473	
Hospital Staff Position	Number	Percent
Verpleegkundig specialist / master verpleegkundige	76	9
Bachelor verpleegkundige (HBO6)	267	30
Gegradueerd verpleegkundige (HBO5)	164	18
Zorgkundige	25	3
Arts-assistent in opleiding	2	0,2
Arts	61	7
Diëtist	4	0,5
Apotheker	11	1
Kinesitherapeut, ergotherapeut, logopedist	31	4
Psycholoog	16	2
Maatschappelijk werker / sociaal verpleegkundige	9	1
Technoloog (EKG, Laboratorium, Radiologie)	14	2
(Adjunct-)hoofdverpleegkundige, programmamanager, middenkader, teamleider	55	6
Directie	3	0,3
Medewerker technische dienst	1	0,1
Medewerker voeding	2	0,2
Medewerker huishouding / schoonmaak	5	0,6
Medewerker informatietechnologie (IT)	8	1
Medewerker beveiliging	0	0
Medewerker logistiek, patiënt-/goederentransport	4	0,5
Afdelingsmedewerker, secretaresse, receptionist, kantoormedewerkers	75	9
Andere	48	5
Total	881	100,4
Tenure in Hospital	Number	Percent
Minder dan 1 jaar	67	8
1 tot 5 jaar	216	25
6 tot 10 jaar	142	16

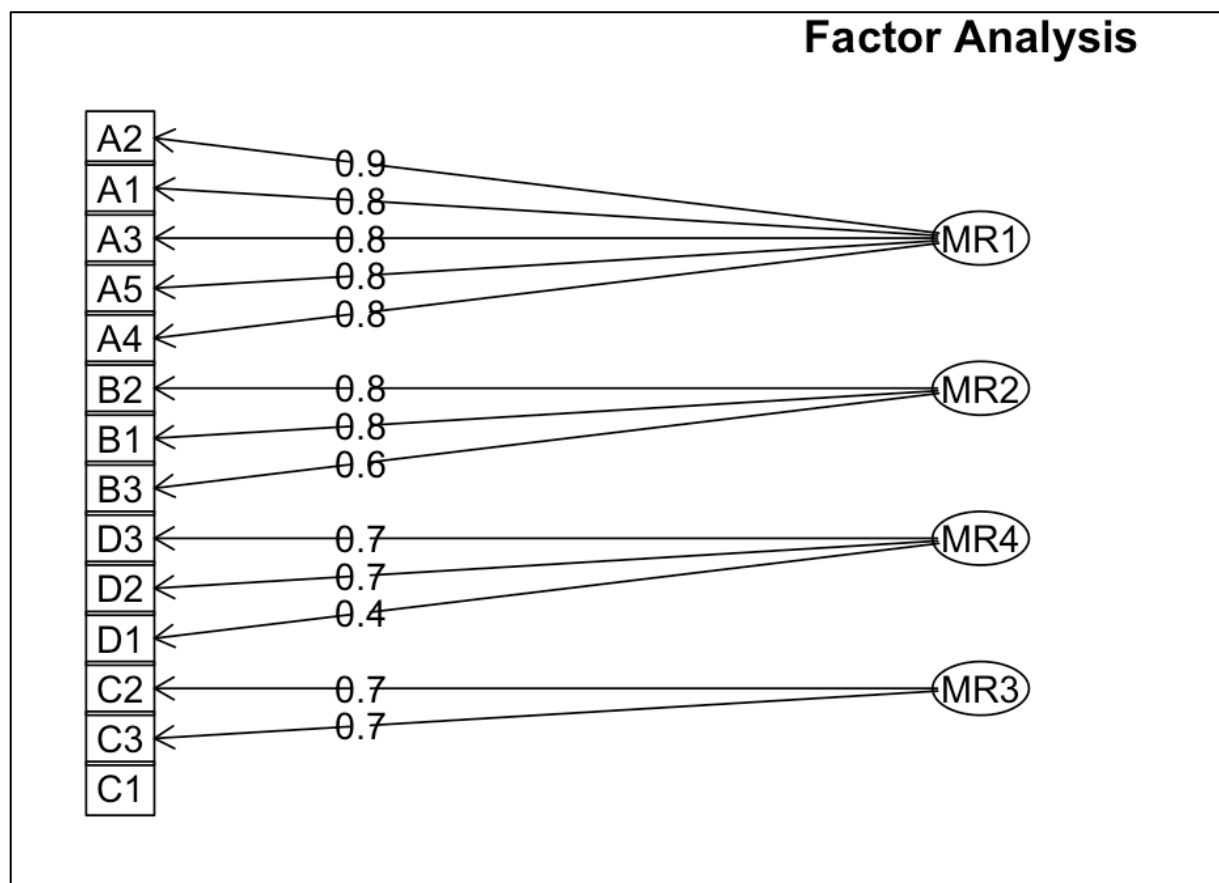
11 of meer jaren	447	51
Total	872	100
N/A	9	
General total	881	
Tenure in Unit/ Work Area	Number	Percent
Minder dan 1 jaar	83	10
1 tot 5 jaar	274	31
6 tot 10 jaar	148	17
11 of meer jaren	365	42
Total	870	100
N/A	11	
General total	881	
Hours Worked per Week in Hospital	Number	Percent
Minder dan 30 uur per week	160	19
30 tot 40 uur per week	587	67
Meer dan 40 uur per week	125	14
Total	872	100
N/A	9	
General total	881	
Interaction With Patients	Number	Percent
JA, ik heb doorgaans direct contact met patiënten	767	88
NEE, ik heb doorgaans GEEN direct contact met patiënten	104	12
total	871	100
N/A	10	
General total	881	

Appendix G table 6

Append table 6: Cronbach Alpha HIT

Dimension	Item	CI 95%	Cronbach's Alpha if item deleted	Cronbach's Alfa
1) EPD Systeem training		0,76-0,81		0,79
	B1		0,7	
	B2		0,67	
	B3		0,78	
2) EPD systeem ondersteuning en communicatie		0,76-0,81		0,78
	D1		0,79	
	D2		0,68	
	D3		0,64	
3) EPD patiëntveiligheid en kwaliteit problemen		0,92-0,93		0,92
	A1		0,91	
	A2		0,9	
	A3		0,91	
	A4		0,91	
	A5		0,91	
4) EPD en workflow/werkproces		0,6-0,68		0,64
	C1		0,74	
	C2		0,35	
	C3		0,43	

Appendix H figure 2



Append figure 2: Exploratory Factor Analysis HIT