Development and Validation of the QUALI-PALLI-FAM Questionnaire for Assessing Relatives' Perception of Quality of Inpatient Palliative Care: A Prospective Cross-Sectional Survey

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Development and validation of the QUALI-PALLI-FAM questionnaire for assessing relatives' perception of quality of inpatient palliative care: A prospective cross-sectional survey

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Number of tables: 5

Number of figures: 1

Number of references 63

Word count: 3455

Number of addition files: 5

Abstract

Context

Relatives of patients receiving palliative care are at risk for psychological and physical distress, and their perception of quality of care can influence patients' quality of life.

Objectives

The purpose of this study was to develop and validate the QUALI-PALLI-FAM questionnaire to measure families' perception of and satisfaction with palliative care.

Methods

An exploratory factor analysis was conducted, and we evaluated the questionnaire's internal consistency using Cronbach's alpha, its stability across various strata, and the correlation between the QUALI-PALLI-FAM (factors, total score, and global satisfaction) and the total score of the FAMCARE questionnaire.

Results

This multicentric prospective cross-sectional survey was conducted in seven French hospitals, namely, three palliative care units and four standard medical units with a mobile palliative care team. The questionnaire was completed by 170 relatives of patients (over 90% of patients had advanced cancer). The final questionnaire included 14 items across three domains: organisation of care and availability of caregivers, medical information provision, and confidence and involvement of relatives. Internal consistency was good for all subscales (Cronbach's α: 0.74–0.86). Our questionnaire was stable across various strata: age and gender (patients and relatives), Palliative Performance Scale scores, and care settings. The QUALI-PALLI-FAM total score was correlated with the total FAMCARE score.

Conclusion

The QUALI-PALLI-FAM appears to be a valid, reliable, and well-accepted tool to explore relatives' perception of quality of inpatient palliative care and complements the QUALI-PALLI-PAT questionnaire. Further testing is required in various settings and countries.

Key words: palliative care, quality of health care, outcome measure, questionnaire, validation study, family

Running title:

Relatives' perception of quality of care

Key message

The QUALI-PALLI-FAM questionnaire appears to be a valid and reliable tool to assess relatives' perception of and satisfaction with the quality of palliative care. It explores three domains: organisation of care and availability of caregivers, medical information provision, and confidence and involvement of relatives. It complements the patient questionnaire QUALI-PALLI-PAT.

Introduction

The quality of life of patients confronting the end stage of their life may be severely compromised without the support of relatives. However, being a relative of a palliative care patient is challenging, and many relatives experience a wide range of problems, such as physical and psychological exhaustion.[1–4] Another cause of suffering for relatives is dissatisfaction with the medical information they receive and their involvement in care.[5] Unsolved problems or unmet caregiver needs may not only decrease their own quality of life but also affect patients' health outcomes negatively,[6–9] as there is an interdependence between patients' quality of life and relatives' burden.[10] Moreover, negative perceptions of the quality of end-of-life care are significantly associated with complicated grief.[11]

Family support is an essential task in palliative care, which is often described as patient/family-centred care.[12] Teams should systematically address the concerns and needs of relatives to offer them tailored support. Randomised studies have demonstrated that early palliative care can improve relatives' quality of life and satisfaction with care.[13,14] Relatives' perception of quality of care is thus a major outcome.[15,16] Furthermore, identifying the opinions of patients is more difficult in the terminal phase, which adds value to relatives' viewpoints.[17]

In a recent review, the priorities in end-of-life care identified by patients and their families were expert care, effective communication and shared decision-making, respectful and compassionate care, adequate environment for care, family involvement, and support with financial affairs.[18,19] Systematic reviews have identified instruments for evaluating the quality of palliative care and different concepts have been addressed, such as end-of-life care experience, satisfaction with care, and caregivers' well-being.[20,21] Two Canadian psychometric questionnaires assessing family caregivers' satisfaction with care have been extensively used, namely the CANHELP and FAMCARE-2 questionnaires.[22–31]

Our research program, the "QUALI-PALLI project" aims to obtain a comprehensive assessment of palliative care including (i) the patient's point of view, (ii) relatives' perspectives, (iii) file review for care assessment, and (iv) professional caregivers' well-being.[15,32] To ensure coherency, we developed our own instruments and refrained from using existing questionnaires, regardless of their quality. The aim of the present study was to develop and validate the QUALI-PALLI-FAM questionnaire to assess relatives' perception of and satisfaction with quality of care in various palliative care settings.

Methods

Development of the QUALI-PALLI-FAM questionnaire

The Quali-Palli project[32] was approved by a regional ethics committee including patient representatives (CPP IDF-XI, #12059, 2012-09-24).

A multidisciplinary steering committee of palliative-related professionals (physicians, nurses, psychologists, social workers, and volunteers) developed a 45-item questionnaire based on our initial qualitative study and relevant literature.[15,33] Four domains were included: quality of information about health status and care of relatives (3 items), relation with physicians and caregivers (11 items), well-being of relatives (10 items), and functioning of the unit (21 items; Table 1). Items were rated on a 4-point Likert-type scale ('no, not at all'; 'not really'; 'almost'; 'yes, exactly') or as 'Does not apply to

me or my relative' (i.e. not applicable). A 46th item assessed global satisfaction with palliative care on a 4-point scale.

To assess the face validity of the questionnaire, twelve relatives from three different settings, participated in a pilot study where they completed the initial version of the questionnaire and rated items in terms of wording, understanding, relevance, and any offensive issues.[34]

Clinical study

A cross-sectional study was conducted in the Paris region of France in seven sites pertaining to two categories: three hospital-based palliative care units (PCUs) and four standard medical units with a mobile palliative team. Relatives were eligible if they were fluent in French and had a related adult patient hospitalised for palliative care for more than 72 hours with a life expectancy of under 3 months.

At each site, one trained research assistant asked the health care team (without involving patients) to indicate the relatives who were present at the patients' bedside, among family members, friends, and neighbours. The research assistant met the relatives during a visit to either the PCU or standard medical unit, provided them with information, and invited them to participate in the study, reassuring them about confidentiality concerns and independence from the palliative care team and hospital. After providing verbal consent, the relatives completed the written version of QUALI-PALLI-FAM questionnaire and the FAMCARE scale (French version, 20 items), which has been used in different advanced cancer care settings to assess relatives' satisfaction with care.[35,36]. Relatives completed both measures independently without a researcher present at all. The questionnaire was hand-delivered to the research assistant or delivered via mail using pre-paid postage without interaction between the relatives and the local team. The Palliative Performance Scale (PPS v2) was completed using data from the patient's file to determine the patient's palliative performance status.[37,38] We planned to recruit around 30 relatives per site and 5 respondents per item, for 210−220 respondents in total.[39–41]

Statistical analyses

Item responses were re-scaled to range between 1 ('no, not at all') and 4 ('yes, exactly'), with eventual inversion so that higher scores indicated higher care quality. Not applicable (NA) responses and missing data (MD) were considered to be a non-response (NR). Acceptability was estimated based on the proportion of MD per item and overall.

Item analysis

Items were tagged for removal if they showed any of the following: high rate of NR (≥ 25%), floor or ceiling effects (≥ 90% of extreme-category responses), or redundancy between items (polychoric correlation R > 0.70). The choice of removal was moderated by the steering committee as a function of the clinical relevance or interest shown in the literature or in our qualitative study.[15] Due to the 'all-structures all settings' principle of our project, an item considered interesting for one care setting may have been retained despite poor overall performance.

We analysed the response distribution according to the age and gender of relatives and patients, relationship with the patient, PPS score, and type of setting.

Factorial structure

Subsequently, considering the remaining items, participants with more than one-third of the items considered NR, or more than nine-tenths of them showing ceiling effects, were henceforth withdrawn.

Exploratory factor analysis (EFA) was then used to reveal the underlying structure of the items. To jointly deal with MD and robustness issues, we considered the following proposals.[42] When using multiple imputations prior to the EFA, the eigenvector may mutate from one imputation to another, so averaging the eigenvectors becomes meaningless. Thus, we estimated one correlation matrix from all the matrices issued from imputed datasets, using Rubin's rule, then applied the EFA on this unique synthesis matrix. Missing responses were imputed from a model considering seven covariates, namely age and gender of relatives and patients, relative relationship, site, and PPS score, by using the 'mice' procedure from the mifa R package.[43] A total of 200 imputations (10 iterations each) were performed. Global satisfaction and FAMCARE scores were not imputed.

The suitability of the imputed data for EFA was assessed using Bartlett's sphericity test, completed for each item with the Kaiser–Meyer–Olkin (KMO) test and squared multiple correlations (SMC). Responses being ordinal, a polychoric correlation matrix was calculated, and the extraction of factors used the 'minimum residuals' method, free from distributional assumptions. Anticipating some inter-factor correlations, an oblique rotation (promax) of the solution was performed.[44] Parallel analysis[45] and minimum average partial (MAP) correlation[46] were used to identify the number of factors to extract.

The retention of items involved predetermined criteria: KMO (> 0.5) and SMC (> 0.3), loading (≥ 0.35), separation (minimal difference between the two top loadings ≥ 0.1), uniqueness (< 0.75), complexity (< 2.5), and Cronbach's alpha gain for the related factor when the item is dropped (< 0.05). Concurrent solutions were compared with the Bayesian information criterion (BIC).[47] Within each subscale, a mean subscore was generated by summing all item scores divided by the number of items.

Subsequently, reliability was assessed, first with Cronbach's α, globally and for any identified factor (subscale), then also with beta coefficients[48] and Guttman's G6, as alpha coefficients may be biased for ordinal data.[49] We used the psych R package [50]

Consistency was also evaluated by calculating (i) the average inter-item correlations within subscales,[51,52] (ii) the correlation of items in one subscale with the other subscales, and (iii) item-total correlations.[53] The independence of dimensions was ascertained from the inter-subscale correlation matrix.[54]

The stability of the solution was checked (i) by performing EFA using either Spearman correlations, the principal components extraction method, or oblimin rotation, (ii) by averaging statistics calculated on data at each imputation cycle instead of calculating statistics on unique 'synthesis' data, and (iii) by comparing scores across different strata of relatives, patients, care settings, and also a random split. Finally, the same EFA procedure was conducted independently on participants in the strata formed by each characteristic, then structural replicability was estimated from the proportion of items that were attributed to the same factors across the strata; for concordant pairs, the paired absolute difference indicated whether the loadings were close in magnitude.

For all tests, bilateral statistical significance was set at .05, without any adjustment for multiplicity.

Content validity

The steering committee interpreted the results of the EFA, focusing on the clinical sense of the subscales.

Reproducibility

Test-retest procedures should show the stability of the scores over time when no change has occurred. The delay between two tests must be long enough to prevent recall bias, but short enough to ensure absence of changes in care or patient status, which are infrequent at the end of life.[20]

Criterion-related validity

The relationships of QUALI-PALLI-FAM factors and global satisfaction with FAMCARE scores were assessed using Spearman correlations.

The QUALI-PALLI-FAM was not conceived in order to obtain a proxy measure of care quality from a relative instead of from a given patient, which is why we did not sample pairs of patients and their own relatives. By sampling patients (data taken from the QUALI-PALLI-PAT study [32]) and relatives separately, our goal was to obtain two parallel but independent measures of care provided at a site. Thus, comparisons of mean scores from the two questionnaires, the QUALI-PALLI-FAM and QUALI-PALLI-PAT (concerning unrelated patients), were performed at each site to investigate the congruence between patients' and relatives' perspectives.[32]

Results

Description of study population

From March 2012 to April 2014, 170 relatives of palliative inpatients (90% had advanced stage cancer) completed the 46-item questionnaire; however, one site withdrew, thus preventing us from reaching the target sample size (Table 2). Twenty-one participants were excluded because of MD or ceiling effects; their characteristics were similar to those of the remaining ones, except that the remaining participants were more likely to be a spouse/partner of the patient (33% vs. 58%, p = 0.06; data not reported).

Face validity

The 12 pilot testers easily completed the questionnaire, with all items being fully understood. Thus, the initial version was left unmodified. In the clinical study, 104 participants (61.2%) provided questionnaires without MD but with some NA responses. Globally, 14.5% of the responses were missing (1106/7650); 21 questionnaires had either too many NR items (n = 11) or items with ceiling effects (n = 10).

Item selection

MD per item ranged from 0% to 7.6%. A total of 19 items presented a high rate of NR (n = 12) or ceiling effects (n = 14). However, due to our initial qualitative study, items 15 (pain relief), 20−21 (help and dignity), 29−32 (volunteers), 34−36 (staying with patient), and 41−45 (social or psychological support) were included in the analysis.[15] When pairs of items were highly correlated ($r \geq 0.70$; $p < 0.0001$; items 10−11; 29−30; 31−32; 41−42; 43−44), the steering committee favoured items showing necessary improvements (depending on the structure, notably) or focused on the relative instead of the patient; thus only 9 items were discarded, leaving 36 items (Table 1).

Construct validity

The KMO was 0.64, and Bartlett's test was significant, indicating that the sample was adequate for EFA. After imputations, EFA on the resulting matrix of 36 items identified either a three- or four-factor solution, as indicated by parallel analysis and MAP. On each initial solution, descending procedures led to a final set of 14 items across three factors. With regard to our qualitative study, 'Involvement with care' (item 13) was maintained despite cross-factoring, as well as 'philosophical or religious support of the patient' despite an unfavourable response distribution (40% NA).

The three factors could be interpreted as (i) organisation of care and availability of caregivers (6 items); (ii) medical information provision (4 items); and (iii) rest, confidence, and involvement of the relatives (4 items). This solution accounted for 62% of the total variance, while the model fit was quite good (root mean square error of approximation = 0.079). Table 3 shows the item loadings by factor, with their quality criteria. Average communality was 0.52. All items except two had a strong loading on only one factor, and the average load by factor was over 0.6 (Table 4). Therefore, the final QUALI-PALLI-FAM questionnaire included 14 specific items plus the item on global satisfaction.

Consistency

The mean subscale scores indicated a high level of satisfaction (Table 4). Cronbach's alpha was high overall (0.97) and good for all factors. Accordingly, reliability based on beta coefficients and Guttman G6 was good. The inter-item correlations indicated an adequate level of homogeneity (Table 4). Item-total correlations and item-scale correlations for the item's own subscale indicated internal consistency (Supplementary File 1). Inter-subscale correlations evidenced independence of factors (Supplementary File 2).

Stability

We confirmed the stability of the questionnaire by obtaining similar combinations of items within factors using either a Spearman correlation matrix, a principal axis factorisation method, or an oblimin rotation, except for item 13, which was moved once from factor 2 to factor 3 (not presented).

Factorisations performed across strata of characteristics showed consistency: more than two-thirds of items belonged to similar factors, except for patient's age, relative relationship, and of course random split (100% agreement; Supplementary File 3a). The mean subscale scores were similar regardless of the characteristics of relatives or patients (Supplementary File 3b), but scores were higher, as expected, when general satisfaction was high, and also PCUs. These setting-related differences ranged from 0.2 to 0.4, while the difference between moderate and high satisfaction was approximately 0.3. When these comparisons between strata were performed at each of the 200

imputations and then summarised (data not shown), conclusions were roughly the same as those presented above, obtained on the final synthesis matrix.

Reproducibility

As the patients' conditions were too unstable, only 10 relatives performed the retest procedure, preventing statistical analysis.

External validation

FAMCARE scores were high (mean = 4.19, SD = 0.64). Global satisfaction with care ($r = 0.56$, $p < 0.001$), and subscale scores of the QUALI-PALLI-FAM were moderately correlated with FAMCARE scores, with the best correlation being with the QUALI-PALLI-FAM total score ($r = 0.71$, $p < 0.001$; Table 5).

The average global satisfaction scores from the QUALI-PALLI-FAM and QUALI-PALLI-PAT ranked the sites in the same order, but patients systematically tended to give higher scores than relatives (Figure 1 and Supplementary File 4).

Discussion

Our study involved the development and validation of the QUALI-PALLI-FAM questionnaire for assessing the quality of palliative care from the perspective of patients' relatives. This questionnaire contains 14 items exploring three domains: organisation of care and availability of caregivers; medical information provision; and confidence and involvement of relatives.

The QUALI-PALLI-FAM complements our patient multidimensional questionnaire, the QUALI-PALLI-PAT.[32] Each domain of the QUALI-PALLI-PAT except one (i.e. possibility for the patient to refuse care or volunteers) has one or more corresponding items on the QUALI-PALLI-FAM. This allows us to consider the concerns of patients and relatives regarding similar topics. Conversely, only two items were specific to the QUALI-PALLI-FAM: confidence in the team (item 39) and appreciation of patient's well-being (item 22). The three domains explored by the QUALI-PALLI-FAM are in agreement with the results of previous qualitative studies.[16,55] Our results highlight that the availability of professional caregivers is an essential component of the quality of palliative care, and this aspect has been understated in previous questionnaires.[15,32,55] Medical communication and involvement in care were also reported as essential factors of quality care, although these aspects of care are not a priority for health care professionals.[56–58] Our study shows that the layout of the unit and rooms was a key point for the perception of quality of care, as was the atmosphere of the setting, which again distinguishes patients and relatives from professionals.[16]

Our study shows that relatives rated the quality of care as high globally and for each of the three subscales. This high level of satisfaction is frequently observed in clinical trials, and the ceiling effects limit the comparison of various palliative settings. However, we observed higher scores on the three subscales in PCUs. This might be because PCUs may be considered the gold standard, providing extensive support and having abundant resources and highly trained staff.[16,27,28,59]

The robust method used to develop and validate the QUALI-PALLI-FAM makes it a sound and valid instrument, which meets most of the criteria formalised in the COSMIN checklist

(www.cosmin.nl/cosmin_checklist.html).[60,61] The instrument was developed based on a conceptual model, with a target population and a delineated context of use. The content relied on a previous qualitative study, and concept elicitation was completed through a pilot test of comprehensibility. Construct validity was based on EFA, while the stability of the structure was checked against several factors. A satisfactory interpretation of the final subscales was achieved. The stability observed in the three domains regardless of the characteristics of patients and relatives allows the QUALI-PALLI-FAM to be used irrespective of the case-mix of patients. The stability across various settings was a key result allowing comparison between PCUs and standard medical wards with palliative care teams. Differences in satisfaction according to relatives' gender or age were weak, thus not supporting Porter's discrepancy theory.[62]

Several limitations to this study should be mentioned. First, the health care team and research assistant discussed the choice of family members, which may have caused selection bias. An independent selection method needs to be used in the future. Second, relatives may have withheld their criticisms or complaints so as not to risk displeasing the health care team.[28] However, as the questionnaires were provided in a written format by a research assistant independent of the health care team, this risk may have been reduced. Third, the total sample size was smaller than expected, which prevented us from performing a sample split for a confirmatory factorial analysis on the second subsample. Our sample size nevertheless appeared sufficient both in view of the responder-to-item and mean item-to-factor ratios, and the high value of the loadings, averaging near 0.7 for each factor, while the structure appeared stable.[63] Fourth, the study found a relatively high proportion of items with ceiling effects and NA responses, which may reflect the top-notch palliative services provided by a team already committed to a high-quality approach. Finally, it was not possible to conduct test-retest validation, as patients' length of stay was too short (median around 12 days). A period of 48 hours after admission was necessary before completing the questionnaire, and patients' clinical conditions were too unstable. For the same reason, we could not assess inter-rater reliability.

Conclusion

The QUALI-PALLI-FAM questionnaire appears to be a valid, reliable, and well-accepted French-language tool that assesses the quality of and satisfaction with inpatient palliative care from the point of view of patients' relatives, and can be used in combination with the patient questionnaire QUALI-PALLI-PAT (Supplementary File 5; French version). Tested in different types of palliative care wards, the QUALI-PALLI-FAM questionnaire is usable as a 'one-size-fits-all' questionnaire for inpatient palliative care. The shortness of the final form allows its periodic use to evaluate the quality of care through its three domains. A larger study involving a higher number of settings and participants is nevertheless mandatory to assess the promises of this tool.

The QUALI-PALLI-FAM and QUALI-PALI-PAT results highlight the importance of caregivers' availability. Quality of care does not only depend on the effectiveness of technical care (i.e., time spent in quantifiable clinical interactions) but also on the creation of a caregiver–patient relationship. This relationship requires caregivers to be available for informal interactions, which are neither quantifiable nor predictable. Consequently, a purely accounting and technical management of caregivers' working time would lead to a decline in the overall quality of palliative care.

Disclosures and Acknowledgements

Conflicts of interest: The authors declare that they have no competing interests

Acknowledgements: The investigators thank the members of the Quali-Palli Group: Anne Abel, Laure Copel, Louise Geoffroy, Laurence Gineston, Hélène Godard, Xavier Grenet, Karima Nfissi, Jean-François Richard, Sylvie Rostaing, Yael Tibi-Lévy, Isabelle Vedel, Kate Vincent, and the Clinical Research Unit team that worked on Quali-Palli (Layde Meaude, Sylvie Laot-Cabon, Sarah Gaston-Dreyfus, Audrey Angelard, Yasmine Saidji, Karima Mesbahi, and Wen Teng).

Authorship: FG and PA were responsible for the study concept and design, obtained funding, and supervising the study. PA and PMS carried out the statistical analysis. The QUALI-PALLI Group conducted the literature review and selected the first set of items. All authors analysed and interpreted the data. FG, PA, and CB drafted the manuscript. All authors critically revised the manuscript, read, and approved the final version of the manuscript.

Funding: This study was supported by a grant from the French Ministry of Health (PreQHos 2009–04) and sponsored by the Assistance Publique-Hôpitaux de Paris (NI10052).

Ethics and consent: This study was approved by a regional ethics committee (#12059, Comité de Protection des Personnes 'CPP île de France XI', Saint Germain-en-Laye, France) and was registered on clinicaltrials.gov (NCT02814682). All participants were duly informed and oral consent was obtained prior to the research. According to French health regulations, no written informed consent was required, as this was an observational study using registered data.

Data sharing: The datasets generated and/or analysed during the current study are not publicly available to protect confidentiality, but aggregated data are available from the corresponding author on reasonable request.

References

[1] Cui J, Song LJ, Zhou LJ, Meng H, Zhao JJ. Needs of family caregivers of advanced cancer patients: a survey in Shanghai of China: Needs of family caregivers of advanced cancer patients. Eur J Cancer Care (Engl) 2014;23:562–9. https://doi.org/10.1111/ecc.12174.

[2] Oechsle K, Ullrich A, Marx G, Benze G, Heine J, Dickel L-M, et al. Psychological burden in family caregivers of patients with advanced cancer at initiation of specialist inpatient palliative care. BMC Palliat Care 2019;18:102. https://doi.org/10.1186/s12904-019-0469-7.

[3] Ullrich A, Ascherfeld L, Marx G, Bokemeyer C, Bergelt C, Oechsle K. Quality of life, psychological burden, needs, and satisfaction during specialized inpatient palliative care in family caregivers of advanced cancer patients. BMC Palliat Care 2017;16:31. https://doi.org/10.1186/s12904-017-0206-z.

[4] Wang T, Molassiotis A, Chung BPM, Tan J-Y. Unmet care needs of advanced cancer patients and their informal caregivers: a systematic review. BMC Palliat Care 2018;17:96. https://doi.org/10.1186/s12904-018-0346-9.

[5] Naoki Y, Matsuda Y, Maeda I, Kamino H, Kozaki Y, Tokoro A, et al. Association between family satisfaction and caregiver burden in cancer patients receiving outreach palliative care at home. Palliat Support Care 2018;16:260–8. https://doi.org/10.1017/S1478951517000232.

[6] Carolan CM, Smith A, Forbat L. Conceptualising psychological distress in families in palliative care: Findings from a systematic review. Palliat Med 2015;29:605–32. https://doi.org/10.1177/0269216315575680.

[7] Milbury K, Badr H, Fossella F, Pisters KM, Carmack CL. Longitudinal associations between caregiver burden and patient and spouse distress in couples coping with lung cancer. Support Care Cancer 2013;21:2371–9. https://doi.org/10.1007/s00520-013-1795-6.

[8] Sharpe L, Butow P, Smith C, McConnell D, Clarke S. The relationship between available support, unmet needs and caregiver burden in patients with advanced cancer and their carers. Psychooncology 2005;14:102–14. https://doi.org/10.1002/pon.825.

[9] Zwahlen D, Hagenbuch N, Jenewein J, Carley MI, Buchi S. Adopting a family approach to theory and practice: measuring distress in cancer patient-partner dyads with the distress thermometer. Psychooncology 2011;20:394–403. https://doi.org/10.1002/pon.1744.

[10] Krug K, Miksch A, Peters-Klimm F, Engeser P, Szecsenyi J. Correlation between patient quality of life in palliative care and burden of their family caregivers: a prospective observational cohort study. BMC Palliat Care 2016;15:4. https://doi.org/10.1186/s12904-016-0082-y.

[11] Miyajima K, Fujisawa D, Yoshimura K, Ito M, Nakajima S, Shirahase J, et al. Association between Quality of End-of-Life Care and Possible Complicated Grief among Bereaved Family Members. J Palliat Med 2014;17:1025–31. https://doi.org/10.1089/jpm.2013.0552.

[12] Hudson P, Payne S. Family Caregivers and Palliative Care: Current Status and Agenda for the Future. J Palliat Med 2011;14:864–9. https://doi.org/10.1089/jpm.2010.0413.

[13] El-Jawahri A, Greer JA, Pirl WF, Park ER, Jackson VA, Back AL, et al. Effects of Early Integrated Palliative Care on Caregivers of Patients with Lung and Gastrointestinal Cancer: A Randomized Clinical Trial. The Oncologist 2017;22:1528–34. https://doi.org/10.1634/theoncologist.2017-0227.

[14] Dionne-Odom JN, Azuero A, Lyons KD, Hull JG, Tosteson T, Li Z, et al. Benefits of Early Versus Delayed Palliative Care to Informal Family Caregivers of Patients With Advanced Cancer: Outcomes From the ENABLE III Randomized Controlled Trial. J Clin Oncol 2015;33:1446–52. https://doi.org/10.1200/JCO.2014.58.7824.

[15] Vedel I, Ghadi V, Lapointe L, Routelous C, Aegerter P, Guirimand F. Patients', family caregivers', and professionals' perspectives on quality of palliative care: A qualitative study. Palliat Med 2014;28:1128–38. https://doi.org/10.1177/0269216314532154.

[16] Wentlandt K, Seccareccia D, Kevork N, Workentin K, Blacker S, Grossman D, et al. Quality of Care and Satisfaction With Care on Palliative Care Units. J Pain Symptom Manage 2016;51:184–92. https://doi.org/10.1016/j.jpainsymman.2015.10.006.
[17] McPherson CJ, Addington-Hall JM. Judging the quality of care at the end of life: can proxies provide reliable information? Soc Sci Med 2003;56:95–109. https://doi.org/10.1016/S0277-9536(02)00011-4.
[18] Virdun C, Luckett T, Davidson PM, Phillips J. Dying in the hospital setting: A systematic review of quantitative studies identifying the elements of end-of-life care that patients and their families rank as being most important. Palliat Med 2015;29:774–96. https://doi.org/10.1177/0269216315583032.
[19] Virdun C, Luckett T, Lorenz K, Davidson PM, Phillips J. Dying in the hospital setting: A meta-synthesis identifying the elements of end-of-life care that patients and their families describe as being important. Palliat Med 2017;31:587–601. https://doi.org/10.1177/0269216316673547.
[20] Albers G, Echteld MA, de Vet HCW, Onwuteaka-Philipsen BD, van der Linden MHM, Deliens L. Evaluation of quality-of-life measures for use in palliative care: a systematic review. Palliat Med 2010;24:17–37. https://doi.org/10.1177/0269216309346593.
[21] Lendon JP, Ahluwalia SC, Walling AM, Lorenz KA, Oluwatola OA, Anhang Price R, et al. Measuring Experience With End-of-Life Care: A Systematic Literature Review. J Pain Symptom Manage 2015;49:904-915.e1-3. https://doi.org/10.1016/j.jpainsymman.2014.10.018.
[22] Heyland DK, Cook DJ, Rocker GM, Dodek PM, Kutsogiannis DJ, Skrobik Y, et al. Defining priorities for improving end-of-life care in Canada. CMAJ Can Med Assoc J J Assoc Medicale Can 2010;182:E747-752. https://doi.org/10.1503/cmaj.100131.
[23] Heyland DK, Jiang X, Day AG, Cohen SR. The Development and Validation of a Shorter Version of the Canadian Health Care Evaluation Project Questionnaire (CANHELP Lite): A Novel Tool to Measure Patient and Family Satisfaction With End-of-Life Care. J Pain Symptom Manage 2013;46:289–97. https://doi.org/10.1016/j.jpainsymman.2012.07.012.
[24] Heyland DK, Cook DJ, Rocker GM, Dodek PM, Kutsogiannis DJ, Skrobik Y, et al. The development and validation of a novel questionnaire to measure patient and family satisfaction with end-of-life care: the Canadian Health Care Evaluation Project (CANHELP) Questionnaire. Palliat Med 2010;24:682–95. https://doi.org/10.1177/0269216310373168.
[25] Stajduhar K, Sawatzky R, Robin Cohen S, Heyland DK, Allan D, Bidgood D, et al. Bereaved family members' perceptions of the quality of end-of-life care across four types of inpatient care settings. BMC Palliat Care 2017;16:59. https://doi.org/10.1186/s12904-017-0237-5.
[26] Pereira A, Ferreira A, Abrantes AR, Gomes C, Saraiva J, Teixeira L, et al. Cultural Adaptation and Validation of the Portuguese Version of the CANHELP Lite Bereavement Questionnaire. Healthcare 2020;8:27. https://doi.org/10.3390/healthcare8010027.
[27] Aoun S, Bird S, Kristjanson LJ, Currow D. Reliability testing of the FAMCARE-2 scale: measuring family carer satisfaction with palliative care. Palliat Med 2010;24:674–81. https://doi.org/10.1177/0269216310373166.
[28] Teresi JA, Ornstein K, Ocepek-Welikson K, Ramirez M, Siu A. Performance of the Family Satisfaction with the End-of-Life Care (FAMCARE) measure in an ethnically diverse cohort: psychometric analyses using item response theory. Support Care Cancer 2014;22:399–408. https://doi.org/10.1007/s00520-013-1988-z.
[29] Ornstein KA, Teresi JA, Ocepek-Welikson K, Ramirez M, Meier DE, Morrison RS, et al. Use of an Item Bank to Develop Two Short-Form FAMCARE Scales to Measure Family Satisfaction With Care in the Setting of Serious Illness. J Pain Symptom Manage 2015;49:894-903.e4. https://doi.org/10.1016/j.jpainsymman.2014.10.017.
[30] D'Angelo D, Punziano AC, Mastroianni C, Marzi A, Latina R, Ghezzi V, et al. Translation and Testing of the Italian Version of FAMCARE-2: Measuring Family Caregivers' Satisfaction With Palliative Care. J Fam Nurs 2017;23:252–72. https://doi.org/10.1177/1074840717697538.
[31] Teresi JA, Ocepek-Welikson K, Ramirez M, Ornstein KA, Bakken S, Siu A, et al. Psychometric Properties of a Spanish-Language Version of a Short-Form FAMCARE: Applications to Caregivers

of Patients With Alzheimer's Disease and Related Dementias. J Fam Nurs 2019;25:557–89. https://doi.org/10.1177/1074840719867345.
[32] Guirimand F, Martel-Samb P, Guy-Coichard C, Picard S, Devalois B, Copel L, et al. Development and validation of a French questionnaire concerning patients' perspectives of the quality of palliative care: the QUALI-PALLI-Patient. BMC Palliat Care 2019;18:19. https://doi.org/10.1186/s12904-019-0403-z.
[33] Salomon L, Gasquet I, Mesbah M, Ravaud P. Construction of a scale measuring inpatients' opinion on quality of care. Int J Qual Health Care J Int Soc Qual Health Care 1999;11:507–16.
[34] McColl E, Jacoby A, Thomas L, Soutter J, Bamford C, Steen N, et al. Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients. Health Technol Assess Winch Engl 2001;5:1–256.
[35] Kristjanson LJ. Validity and reliability testing of the FAMCARE Scale: measuring family satisfaction with advanced cancer care. Soc Sci Med 1982 1993;36:693–701.
[36] Ringdal GI, Jordhøy MS, Kaasa S. Measuring quality of palliative care: psychometric properties of the FAMCARE Scale. Qual Life Res Int J Qual Life Asp Treat Care Rehabil 2003;12:167–76.
[37] Legault S, Laurin C, Bouvette M. French version of Palliative Performance Scale v2. PPS 2001. https://victoriahospice.org/wp-content/uploads/2019/07/pps_-_french_-_sample.pdf (accessed July 8, 2020).
[38] Lau F, Downing GM, Lesperance M, Shaw J, Kuziemsky C. Use of Palliative Performance Scale in end-of-life prognostication. J Palliat Med 2006;9:1066–1075.
[39] Beavers AS, Lounsbury JW, Richards JK, Huck SW, Skolits GJ, Esquivel SL. Practical considerations for using exploratory factor analysis in educational research. Pract Assess Res Eval 2013;18.
[40] Kyriazos TA. Applied Psychometrics: Sample Size and Sample Power Considerations in Factor Analysis (EFA, CFA) and SEM in General. Psychology 2018;09:2207. https://doi.org/10.4236/psych.2018.98126.
[41] Stevens JP. Applied Multivariate Statistics for the Social Sciences, Fifth Edition. Routledge; 2012.
[42] Nassiri V, Lovik A, Molenberghs G, Verbeke G. On using multiple imputation for exploratory factor analysis of incomplete data. Behav Res Methods 2018;50:501–17. https://doi.org/10.3758/s13428-017-1013-4.
[43] Software - Exploratory factor analysis of incomplete data — I-BioStat n.d. https://ibiostat.be/online-resources/online-resources/expfactor (accessed May 16, 2020).
[44] Thompson B. Exploratory and confirmatory factor analysis: Understanding concepts and applications. Washington, DC, US: American Psychological Association; 2004. https://doi.org/10.1037/10694-000.
[45] Horn JL. A rationale and test for the number of factors in factor analysis. Psychometrika 1965;30:179–85. https://doi.org/10.1007/BF02289447.
[46] Zwick WR, Velicer WF. Factors Influencing Four Rules For Determining The Number Of Components To Retain. Multivar Behav Res 1982;17:253–69. https://doi.org/10.1207/s15327906mbr1702_5.
[47] Preacher KJ, Zhang G, Kim C, Mels G. Choosing the Optimal Number of Factors in Exploratory Factor Analysis: A Model Selection Perspective. Multivar Behav Res 2013;48:28–56. https://doi.org/10.1080/00273171.2012.710386.
[48] Revelle W, Zinbarg RE. Coefficients Alpha, Beta, Omega, and the glb: Comments on Sijtsma. Psychometrika 2008;74:145. https://doi.org/10.1007/s11336-008-9102-z.
[49] Sijtsma K. On the Use, the Misuse, and the Very Limited Usefulness of Cronbach's Alpha. Psychometrika 2009;74:107–20. https://doi.org/10.1007/s11336-008-9101-0.
[50] Revelle W. psych: Procedures for Psychological, Psychometric, and Personality Research. 2020.
[51] Briggs SR, Cheek JM. The role of factor analysis in the development and evaluation of personality scales. J Pers 1986;54:106–48. https://doi.org/10.1111/j.1467-6494.1986.tb00391.x.
[52] Clark LA, Watson D. Constructing validity: Basic issues in objective scale development. Washington, DC, US: American Psychological Association; 2016. https://doi.org/10.1037/14805-012.

[53] Ware JE. Methods for Testing Data Quality, Scaling Assumptions, and Reliability: The IQOLA Project Approach n.d.:8.
[54] Nunnally JC. Psychometric theory. McGraw-Hill; 1994.
[55] Dy SM, Shugarman LR, Lorenz KA, Mularski RA, Lynn J, RAND-Southern California Evidence-Based Practice Center. A systematic review of satisfaction with care at the end of life. J Am Geriatr Soc 2008;56:124–9. https://doi.org/10.1111/j.1532-5415.2007.01507.x.
[56] Caswell G, Pollock K, Harwood R, Porock D. Communication between family carers and health professionals about end-of-life care for older people in the acute hospital setting: a qualitative study. BMC Palliat Care 2015;14:35. https://doi.org/10.1186/s12904-015-0032-0.
[57] Curtis JR, Patrick DL, Engelberg RA, Norris K, Asp C, Byock I. A measure of the quality of dying and death. Initial validation using after-death interviews with family members. J Pain Symptom Manage 2002;24:17–31.
[58] Higgins PC, Prigerson HG. Caregiver evaluation of the quality of end-of-life care (CEQUEL) scale: the caregiver's perception of patient care near death. PloS One 2013;8:e66066. https://doi.org/10.1371/journal.pone.0066066.
[59] Lo C, Burman D, Hales S, Swami N, Rodin G, Zimmermann C. The FAMCARE-Patient scale: Measuring satisfaction with care of outpatients with advanced cancer. Eur J Cancer 2009;45:3182–8. https://doi.org/10.1016/j.ejca.2009.09.003.
[60] Terwee CB, Mokkink LB, Knol DL, Ostelo RWJG, Bouter LM, de Vet HCW. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. Qual Life Res Int J Qual Life Asp Treat Care Rehabil 2012;21:651–7. https://doi.org/10.1007/s11136-011-9960-1.
[61] Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res 2018;27:1159–70. https://doi.org/10.1007/s11136-018-1829-0.
[62] Medigovich K, Porock D, Kristjanson LJ, Smith M. Predictors of family satisfaction with an Australian palliative home care service: a test of discrepancy theory. J Palliat Care 1999;15:48–56.
[63] MacCallum RC, Widaman KF, Preacher KJ, Hong S. Sample Size in Factor Analysis: The Role of Model Error. Multivar Behav Res 2001;36:611–37. https://doi.org/10.1207/S15327906MBR3604_06.

Table 1. Initial questionnaire tested by relatives

For each item, the percentages of uninformative (italicized if ≥ 25%) and ceiling responses (italicized if ≥ 90%) are reported. The 14 items retained in the final questionnaire are in bold type.

		Uninformative response percentage	Ceiling response percentage
Information about health and care of my relative			
	I have received very clear information concerning:		
Q1	- **the evolution of his/her state of health**	4.7	78.4
Q2	- the objective of the treatments (medication, methods)	11.8	83.3
Q3	- **possible adverse effects of treatments**	16.5	64.8
Relations with the doctors and caregivers			
Q4	I know the doctor who deals with my relative	1.8	77.2
Q5	**It is difficult to meet the doctor who deals with my relative**	5.9	9.4
Q6	**The doctors answer all my questions**	4.7	76.5
Q7	My interactions with the doctors take place in a quiet setting, confidentially	7.6	82.2
Q8	The doctor has been disturbed during our exchange	9.4	10.4
Q9	I get information easily from whomever I am talking	3.5	70.1
Q10	The carers are always available to answer to my questions	1.2	80.4
Q11	The carers are available to listen to me	*2.9*	*86.7*
Q12	I feel psychologically supported	15.9	67.8
Q13	**I feel involved in the care and decisions concerning my relative**	8.8	70.3
Q14	*My relative gave his/her consent for me to be informed*	*15.9*	*95.1*
Wellbeing of my relative			
Q15	*The utmost is done to relieve my relative's pain*	*3.5*	*92.1*
Q16	**My relative's pain is quickly taken care of when it is reported**	5.3	89.4
Q17	The utmost is done for my relative to be comfortable	0.6	89.3
Q18	**Carers quickly respond to my relative's requests**	5.3	78.3
Q19	The utmost is done when my relative is anxious, worried, or sad	10.0	75.2
Q20	*My relative receives appropriate help when he/she eats*	*29.4*	*64.2*
Q21	*A bedpan or toileting assistance is offered to him/her in a respectful way*	*31.8*	*91.4*
Q22	**I feel my relative is generally relaxed**	5.3	44.7
Q23	**The bedroom and the unit provide a calm and restful environment**	1.2	81.5

Q24	My relative can rest as much as he/she wishes	2.9	87.3
Functioning of the unit			
Q25	**Caregivers are available**	2.9	80.0
Q26	Doctors are available	7.1	69.6
Q27	**There is excellent coordination in the unit**	14.1	79.5
Q28	*The atmosphere in the unit is very good*	*12.4*	*91.3*
Q29	*I can take advantage of the presence of volunteers if I wish to do so*	*39.4*	*96.1*
Q30	*My relative can take advantage of the presence of volunteers if he/she wishes to do so*	*37.1*	*95.3*
Q31	*My relative feels he/she can refuse the presence of volunteers*	*37.1*	*94.4*
Q32	*I feel I can refuse the presence of the volunteers*	*36.5*	*96.3*
Q33	*I always feel welcome in the unit*	*3.5*	*92.7*
Q34	*I can go to my relative whenever I want*	*1.8*	*98.8*
Q35	*I can stay with my relative for as long as I want*	*2.9*	*97.0*
Q36	*There are good accommodation and catering options available to me*	*34.7*	*80.2*
Q37	**There are places in the unit where I can rest outside the room**	16.5	83.1
Q38	I know that even in my absence, my relative isn't alone	11.2	72.8
Q39	**I am reassured when I leave the unit**	2.9	74.5
Q40	*I have confidence in the care of my relative even in my absence*	*1.2*	*91.7*
Q41	*I can see a psychologist when I need one*	*33.5*	*88.5*
Q42	*My relative can see a psychologist when he/she needs one*	*25.9*	*93.7*
Q43	*I can see a social worker when I need one*	*40.0*	*85.3*
Q44	*My relative can see a social worker when he or she needs it*	*40.0*	*89.2*
Q45	***My relative can talk to someone about philosophical or religious issues if he/she wishes***	*44.1*	*95.8*
Global satisfaction			
Q46	**Overall, what is your level of satisfaction?**		

Table 2. Patient and relative characteristics

Characteristics	Relatives (n=170)	Patients (n=170)
Age (years)		
Mean±SD	59.5±14.7	65.9±15.6
Min-Max	23-95	18-99
<50	26%	
50−59	26%	
60−69	25%	
≥70	23%	
Gender		
Women	65.4%	51.7%
Setting		
No PCU		41%
PPS		
≥60%		12%
40-50%		30%
≤30%		58%
Relationship to patient		
Husband/wife/partner	55%	
Child	21%	
Parent	11%	
Other	13%	

SD: standard deviation; PPS: Palliative Performance Scale (French version 2); PCU: palliative care unit.

Table 3. Exploratory factorial analysis (oblimin rotation): loadings and quality criteria

	Item	F1	F2	F3	Uniqueness	Complexity	KMO	SMC
1	I have received very clear information concerning the evolution of his/her state of health	0.00	**0.73**	0.02	0.45	1.0	0.76	0.55
3	I have received very clear information concerning the possible adverse effects of treatments	0.11	**0.56**	-0.17	0.68	1.3	0.72	0.40
5	It is difficult to meet the doctor who deals with my relative	0.11	**0.57**	0.06	0.57	1.1	0.80	0.51
6	The doctors answer all my question	-0.02	**0.81**	0.01	0.35	1.0	0.74	0.62
13	I feel involved in the care and decisions concerning my relative	-0.27	0.48	**0.52**	0.49	2.5	0.75	0.46
16	My relative's pain is quickly taken care of when it is reported	**0.74**	0.06	-0.15	0.51	1.1	0.82	0.54
18	Carers quickly respond to my relative's requests	**0.69**	0.13	0.11	0.33	1.1	0.86	0.65
22	I feel my relative is generally relaxed	**0.44**	-0.08	0.23	0.69	1.6	0.79	0.40
23	The bedroom and the unit provide a calm and restful environment	**0.61**	0.09	0.07	0.53	1.1	0.85	0.52
25	Caregivers are available	**0.84**	-0.10	-0.06	0.40	1.0	0.78	0.61
27	There's excellent coordination in the unit	**0.73**	0.25	-0.01	0.27	1.2	0.87	0.70
37	There are places in the unit where I can rest outside the room	0.08	0.02	**0.74**	0.37	1.0	0.72	0.58
39	I am reassured when I leave the unit	0.39	-0.15	**0.50**	0.50	2.1	0.84	0.48
45	My relative can talk to someone about philosophical or religious issues if he/she wishes	-0.03	-0.06	**0.68**	0.58	1.0	0.62	0.47

KMO: Kaiser−Meyer−Olkin; SMC: squared multiple correlations; F1, F2, F3: factors.

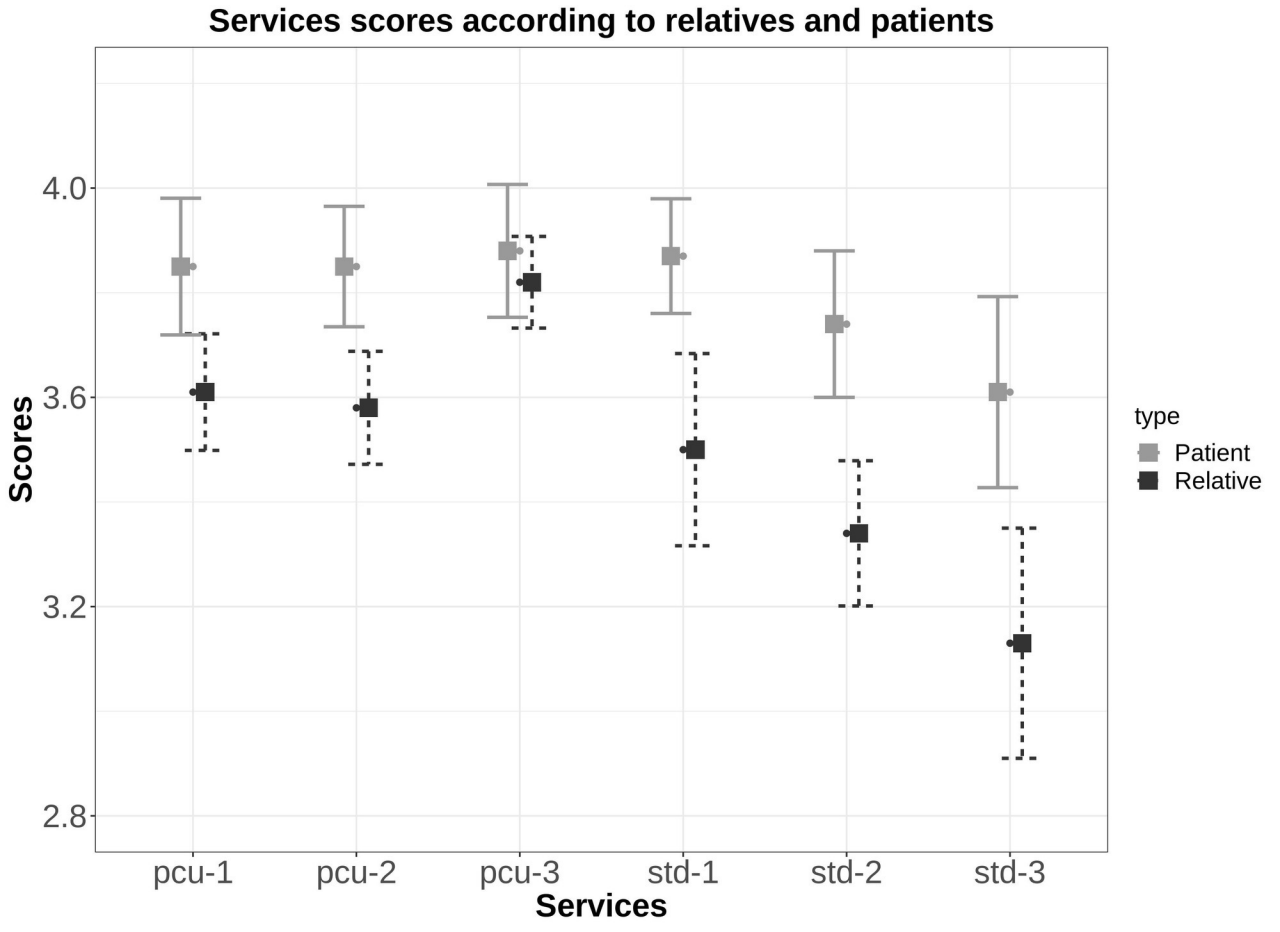
Table 4. Validity of convergence and reliability

Factor	No. items	Loadings mean	Subscale score mean [median] (SD)	Cronbach's α	Beta (minimum split-half reliability)	Guttman G6	Spearman inter-item correlation: mean [median] (min-max)
Factor 1	6	0.68	3.64 [3.83] (0.4)	0.86	0.81	0.88	0.45 [0.46] (0.33-0.53)
Factor 2	4	0.67	3.43 [3.50] (0.6)	0.77	0.68	0.80	0.45 [0.44] (038-0.56)
Factor 3	4	0.61	3.49 [3.75] (0.6)	0.74	0.70	0.78	0.44 [0.42] (0.36-0.54)

Table 5. External validation: correlations of QUALI-PALLI-FAM factors and global satisfaction with FAMCARE scores

	Factor 1	**Factor 2**	**Factor 3**	**Total score**
FAMCARE	0.53, p<0.001	0.63, p<0.001	0.5, p<0.001	0.71, p<0.001
Global satisfaction	0.41, p<0.001	0.34, p<0.001	0.27, p<0.001	0.42, p<0.001

Spearman correlation: rho, two-sided p-value.


Services scores according to relatives and patients
Scores
4.0
3.6
3.2
2.8
pcu-1
pcu-2
pcu-3
std-1
std-2
std-3
Services
type
Patient
Relative