

Empowering parents of Australian infants and children in hospital: Translation, cultural adaptation and validation of the EMPATHIC-30-AUS questionnaire

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ABSTRACT

Objective: To translate, culturally adapt and psychometrically test the EMPATHIC-30 questionnaire in Australian pediatric critical care, neonatal and pediatric ward settings.

Design: Cross-sectional, descriptive, multi-center study conducted in two phases; 1) translation and cultural adaptation, 2) validation of the EMPATHIC-30 questionnaire.

Settings: Two Western Australian sites, the PICU and two pediatric wards of a children's hospital and the neonatal unit of a women's and newborn hospital.

Participants: Parents whose baby or child was admitted to the participating wards or units with a length of hospital stay greater than 24 hours.

Intervention: None

Measurements and main results: Phase 1) A structured 10-step translation process adhered to international principles of good practice for translation and cultural adaptation of patient-reported outcomes. Thirty parents participated in cognitive debriefing. Phase 2) A total of 328 parents responded to the EMPATHIC-30-AUS questionnaire. Reliability was sufficient (Cronbach α at domain level 0.70 – 0.82, for each clinical area 0.56-0.86). Congruent validity was adequate between the domains and three general satisfaction items (r_s 0.38 - 0.69). Non-differential validity showed no significant effect size between three patient or parent demographic characteristics and the domains (Cohen's d less than 0.36). Between the different clinical areas significant differences in responses were found in all domains.

Conclusions: The translated and culturally adapted EMPATHIC-30-AUS is a reliable and valid questionnaire to measure parent reported outcomes in pediatric critical care, pediatric ward and neonatal hospital settings. Using this questionnaire can provide a framework for a standardised quality improvement approach and identification of best practices across specialties, hospital services and for benchmarking similar health services worldwide.

INTRODUCTION

Pediatric and neonatal care involves sick infants, children and adolescents who require treatment, care and guidance tailored to their developmental stage and preferences. Parents play a vital role in the care of their sick child in hospital(1, 2). In addition international best practice encourages healthcare providers to engage with parents to participate in the decision-making process about treatment and care of their child(3). Parents often face critical experiences and are asked to make difficult decisions throughout their child's hospital stay(4). Neonatal or pediatric illness and injury is a stressful experience affecting the entire family (5). Without adequate support, parents can experience significant and persistent distress(6, 7).

Healthcare related quality performance indicators that capture parent and family involvement and patient reported outcomes are receiving increasing attention worldwide(7, 8). Patient satisfaction is now a key measure of quality, yet many satisfaction measurement tools are generic hospital-wide instruments which do not specifically address aspects of different healthcare services(9). Large scale patient satisfaction data can be used for benchmarking and measure the impact of overall hospital performance(10). A limitation of these more general, and usually adult focused, hospital satisfaction instruments is that they may not be derived from a parent or family centred care perspective; the key philosophy underpinning pediatric and neonatal care(11). The use of specific and valid satisfaction instruments is necessary to assess healthcare providers' performance from consumers' perspectives and to identify both best practices and areas for improvement(12). The availability of a valid parent reported outcome measure will enable benchmarking and may contribute to identifying interventions to improve quality of care relevant across the continuum of newborn and pediatric health services.

Latour' s parent satisfaction model for intensive care quality performance and satisfaction with care reflects parental experiences of five family-centred care domains. The EMpowerment of PArents in The Intensive Care (EMPATHIC)

questionnaires were rigorously developed and tested in eight university hospitals' Pediatric Intensive Care Units (PICUs) and Neonatal Units in the Netherlands(13, 14). Further work to develop a more user friendly PICU questionnaire resulted in deletion of statistically redundant items to shorten the original EMPATHIC questionnaire (65 items) to the EMPATHIC 30 item version. The EMPATHIC-30 questionnaire also appeared to be sufficiently generic to be relevant and appropriate to measure parental experiences and satisfaction in pediatric and neonatal settings beyond PICUs.

We hypothesized that the EMPATHIC-30 questionnaire could be used throughout all pediatric and neonatal hospital settings as a standardised measure of parental experience of acute hospital care. This would extend our capacity to understand parents' experience and satisfaction and measure the provision of parent centred care across the whole of their hospital admission. The EMPATHIC 30 was developed and psychometrically tested in Dutch language and to date there is no evidence of a translated and valid English version. To be more widely accessible we felt it was useful to translate the questionnaire into English language and, for the purpose of this research, adapt to our Australian culture. Therefore, the aim of this study was to translate, culturally adapt and psychometrically test the EMPATHIC-30 questionnaire in Australian pediatric critical care, neonatal and pediatric ward settings.

MATERIALS AND METHODS

The cross-sectional descriptive study was conducted across two Western Australian hospitals and involved the 1) translation and cultural adaptation of the EMPATHIC-30 questionnaire and 2) the validation of the questionnaire in the Australian context in the PICU, neonatal unit, and paediatric wards. The responses across the three different settings were also reported. The Human Research Ethics Committees of the two hospital study sites and the university approved the study. Participation was

voluntary and consent was implied by returning a completed anonymous questionnaire.

Settings

Both hospitals provide specialist services. At the children's hospital approximately 250,000 infants, children and adolescents are treated each year. The participating clinical areas at this site were the PICU (10 beds) and two 20-bed pediatric wards (one surgical and one medical ward). The neonatal setting was a designated unit located at the major maternity hospital, the referral centre for complex pregnancies, overseeing over 6000 births per year. The neonatal unit is a 92 bed tertiary referral unit providing intensive care and acute care for over 2300 premature and sick babies each year.

Phase 1: Questionnaire translation

The self-report EMPATHIC-30 questionnaire consists of 30 statements designed to measure parental experiences and satisfaction with care provided by nurses and doctors(15). It is divided into five domains: information (5 items), care and treatment (8 items), parental participation (6 items), organisation (5 items) and professional attitude (6 items). Responses are provided on a six-point scale ranging from 1 *certainly no* to 6 *certainly yes*. A domain mean score of greater than 5 is considered acceptable. A separate box labelled *not applicable* is available for all statements.

A structured 10-step translation process was followed adhering to Wild et al.'s (16) international principles of good practice for translation and cultural adaptation of patient-reported outcomes. Step 1 involved preparation by the researchers working with the instrument developer. Step 2 was the initial forward translation of the EMPATHIC-30 questionnaire from Dutch to English language provided by a Dutch professional interpreter. Step 3 was ensuring this translation was appropriate for the Australian pediatric and neonatal settings included consultation with a health consumer representative from each setting. Step 4 was back translation from English

to Dutch. Step 5 harmonisation included reaching consensus among the research team (including the health consumer representatives). Step 7 cognitive debriefing was undertaken with a convenience sample of 30 parents (10 parents in each of the three clinical areas), whose native language was English and whose characteristics were representative of the target population. The 30 items were provided to the parents with the question: *Is this item understandable and if not, how would you suggest to rephrase it?* The cut-off point for changing an item was 80% of participants. The clarity agreement for all items was greater than 80%. Although suggested changes were made by fewer than 20% of participants, in Step 8 (revision of cognitive debriefing and finalization) the research team agreed to amend the translated version for:

- minor wording changes for clarity such as
 - specify patient age at admission rather than at time of completing questionnaire;
 - describe how long has your baby or child stayed in this unit or ward at time of survey completion;
 - changing the example used on the front cover to clearly demonstrate how to complete the questionnaire;
- consistency in terminology used ie parent or family, team or staff.
- revision of format to improve clarity of item scale ranking (1 to 6), flow of questions from page to page and colour differentiation of questions.

The final questionnaire was proof read (Step 9) and represented the EMPATHIC-30-AUS which was subject to the validity and reliability assessment in Phase 2 (Supplement Digital Content. EMPATHIC 30-AUS). Step 10 is the final report presented in this manuscript.

Phase 2: Questionnaire validation across three different clinical settings

Sample and Recruitment

A non-probabilistic convenience sample was collected between September 2014 and January 2015. The sample size was calculated with the software G * Power 3.1 by referring to the previous work of Latour et al.(13). The sample size was estimated using the ANOVA test (F test) for 3 groups, with a small effect size of 0.2, an adjusted α of 0.02 and a power of 0.8. This resulted in a total of 306 parental responses required (102 responses of parents from each of the three settings).

Participant inclusion criteria were all English speaking parents whose baby or child was admitted to the participating wards or units with a length of stay of at least 24 hours. Exclusion criteria were; parents whose baby or child had died in the hospital or was under the protection of child protective services. This was to avoid any additional burden on parents for the purpose of research. The newly translated questionnaire, the EMPATHIC-30-AUS, was hand-distributed in paper form to parents by a nurse or a midwife at the time of discharge planning (the day before or day of discharge from the unit or ward). One questionnaire per family was given out to parents who were present on the unit or ward as the patient discharge checklist was being completed. During the data collection staff were periodically reminded to distribute the questionnaires. There was no follow up for parents to complete or return the questionnaires which were distributed until the sample size was achieved. A voucher for the value of a cup of coffee was provided for all participants to redeem at the hospital café. Completed questionnaires were returned to a collection box in each of the settings before patient discharge.

Data analysis

Data analysis was undertaken using IBM SPSS Statistics for Windows Version 21.0 (17) and was consistent with the approach previously taken in developing and testing the EMPATHIC-30. Descriptive statistics using counts and percentages and non-parametric tests of difference were reported. Domain means were calculated with not applicable responses and missing data omitted. For non-normally distributed data the

Kruskal Wallis test was used to determine statistical differences of mean ranks between more than 2 groups and post-hoc Dunn-Bonferroni tests for pairwise comparisons. The reliability of the Australian EMPATHIC-30 questionnaire was assessed with the Cronbach's α as a measure of internal consistency of the items within the five domains. A Cronbach's α values of >0.70 were assumed to be satisfactory. (15).

Additionally there were three overall general satisfaction scales which are generally accepted gold standard questions measuring overall satisfaction(13); *I would be happy to return to this unit or ward* (6-point scale); *Overall performance of doctors* and *Overall performance of nurses* (10-point scale). Means and standard deviations were calculated to report the outcome of the satisfaction items.

Spearman's Rank correlation to estimate the relationship between the statements on domain level and the three overall general satisfaction scales was used to examine congruent validity. Non-differential validity testing is undertaken to ascertain that the test measures what it should measure for different subgroups such as population, ethnicity etc. Therefore Cohen's d was used to measure the effect size of standardized mean difference between the domains and three demographic characteristics (planned admission, English as a second language, parent born in Australia). The effect size was classified as small with a value of 0.20, medium with 0.50, and large with >0.80 .(18). For all statistical testing significance was set at a p value of <0.05 .

RESULTS

A total of 328 questionnaires were returned between November 2014 and March 2015 (The number of distributed questionnaires was not recorded so response rate not presented). The characteristics of children and parents are presented in Table 1. The large range of patient age on admission (0 days – 18 years) and length of stay

(1 – 278 days) reflects the patient cohorts across the PICU, neonatal and pediatric clinical areas.

Reliability and validity

The Cronbach's α range at domain level was 0.70 - 0.82 (Table 2). The α value for each clinical area ranged between 0.56 – 0.86. Deletion of individual items did not affect the domain level Cronbach's α . For all domains there were adequate correlations with the three overall satisfaction statements ($r_s = 0.38 - 0.69$) (Table 3). As shown in Table 4 there was no significant difference between the mean scores of the domains and participant characteristics. The effect size measured with Cohen's d was always less than 0.32. The effect size was small with only a medium effect size with the planned / unplanned admission (not statistically significant) in the Organisation domain.

Findings from the questionnaire

The mean domain responses ranged from 5.09 in the Information domain for the neonatal unit to 5.80 in the Professional Attitude domain for PICU (Fig. 1). The mean rank for the total domain score for PICU (199.69) was higher than for wards (150.03) which was higher than for the neonatal unit (146.73). The difference is significant ($H=20.50, 2 \text{ d.f.}, p<0.01$). Post hoc tests showed that PICU was statistically significantly higher than the wards and the neonatal unit (Table 5). Similarly, there were statistically significant differences in mean rank for each domain between clinical areas with PICU mean rank consistently higher in all domains. Table 5 shows the post hoc results for pairwise comparisons for each domain between clinical areas. Interestingly the not applicable (n/a) response type was selected most frequently for two items: *It was easy to speak to the staff caring for my baby or child*

by telephone (n=111, 33.8%) and We were well prepared for our baby or child's discharge by the doctors (n=59, 18%).

DISCUSSION

We have reported the translation, cultural adaptation and validation of the Dutch EMPATHIC-30 questionnaire into the Australian pediatric critical care, neonatal and pediatric ward areas. We used the standardised translation and cultural adaptation process(16) reported by others evaluating the EMPATHIC questionnaire(19, 20) and then replicated and extended the evaluation of the reliability and validity of the newly translated Australian version of EMPATHIC-30. Our work extends the utility of the EMPATHIC-30 to include inpatient settings. This does raise the issue of whether the name remains appropriate. In consultation with the original developer it was agreed to rename the tested instrument Empowerment of Parents of The Hospital In Care-30 -AUS (EMPATHIC-30-AUS).

The EMPATHIC-30-AUS questionnaire reliability and validity testing indicated satisfactory performance in Australian pediatric critical care, neonatal and pediatric ward areas. For reliability assessment, we used Cronbach α to measure the homogeneity of the questionnaire. Whilst there is debate about the best method for reliability estimation, Cronbach's alpha remains the most used and understood (21). When the results across the 3 clinical areas were combined we found the overall Cronbach α at domain level ranged from 0.70 to 0.82. This reflected the Dutch PICU results which ranged from 0.73 to 0.81(15) and indicated overall adequate internal consistency. We did find Cronbach's α domain values <0.70 in the individual settings and these were not improved by removal of items. These findings could be accounted for by the smaller sample sizes in the individual clinical settings compared to the overall reliability testing with more than 300 responses which been recommended when testing an instrument that has many domains and limited in

number of items (21). Therefore further testing with larger sample sizes from each individual area is suggested.

Validity is the extent to which an instrument measures what it is designed to measure and Latour et al. had already demonstrated adequate validity performance for the EMPATHIC-30 in PICU settings (15). In this study we focused on assessing validity in different contexts (the Australian setting for PICU, neonatal and paediatric wards). To achieve that we measured the congruent validity by assessing the correlation of scores with three overall satisfaction measures, ie the same construct. We found the congruent validity was adequate. We also assessed the validity of the questionnaire to ascertain that it meant the same for subgroups of parents such as speaking English as their primary or second language, whether the child's admission was planned or unplanned and whether the parent was born in Australia or overseas. No significant differences in responses between each of these groups were found indicating that each domain of the questionnaire measures what it is intended for each of the subgroups.

Our study results mean that the EMPATHIC-30-AUS questionnaire can be used to make comparisons that are specific enough to be meaningful at individual ward and unit level, yet remain standardised to allow benchmarking between hospitals and between countries where validated translation from Dutch has already been conducted such as Italy(20) and Switzerland(19). Indeed, our study results showed a positive evaluation by parents of the care provided in all settings, yet there were differences found between areas. Parent responses indicated the biggest differences in the provision of information, care and treatment and in organisation at the ward or unit level. Identification of such parent experience differences now provides quality improvement opportunities within the wards, units, hospital services and for benchmarking similar health services elsewhere.

Interpretation of the reasons for the high rate of n/a response selected for two items are not obvious. The response of n/a to *It was easy to speak to the staff caring*

for my baby or child by telephone may relate to the worldwide rapid changes in communication channels since the time of the questionnaire development, or may more specifically reflect the Australian context with a high use of mobile telephones (making redundant the need to call a hospital land-line) and a family member remaining with their child throughout the hospitalization (making redundant the need to speak to staff by telephone). The response of n/a to *We were well prepared for our baby or child's discharge by the doctors* may reflect parents' views that discharge preparation was not the role of doctors, parents' closer interactions with nurses, or the timing of completion of the questionnaire which was prior to being discharged in contrast to Latour et al.'s work where the questionnaire was posted to parents after discharge from hospital. Further exploration is recommended to investigate the basis for this finding. These unanticipated findings highlight how questionnaire development remains a continuing process and further refinement maybe warranted to remain contemporary and relevant.

Some study limitations need to be addressed. Compared to Latour et al.'s Dutch research there were differences in the timing of when we administered the questionnaire. Parents completed the questionnaire in hospital whilst their baby or child was an inpatient rather than a postal survey after discharge. Parents' responses may have been different if completed at home with time to reflect on their experience. Nurses and midwives distributed the questionnaires as part of their clinical practice. The pragmatic approach to questionnaire distribution meant that logistically it was not possible to capture the total number distributed. This way of measuring parent satisfaction is common in hospitals when using the quality improvement approach rather than for the purpose of research. It was also a practical decision to exclude non English speaking participants, with 81% of Australians aged 5 yrs or more who speak only English at home and 2% of Australian families who do not speak any English (22). Interpreter services are used in clinical care but were not used for this research.

This study was conducted in two Western Australian specialty hospital environments where family centred care practices are well embedded. Findings maybe different in general hospital pediatric environments where a family centred care philosophy is less well established.

In conclusion, we have confirmed the translated and culturally adapted EMPATHIC-30-AUS to be a reliable and valid questionnaire for paediatric critical care, pediatric and neonatal hospital settings in the Australian context. Using this questionnaire will provide a framework for a quality improvement approach to measurement of parent centred practices. Parents of children scored PICU performance the highest for each domain. There is an opportunity to examine practices in PICU in more detail to understand the key elements that positively impact on parent experiences and satisfaction so that the same approach can be applied to other clinical areas to optimise and standardise the quality of parents' experiences throughout their hospital stay.

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Figure 1 Domain mean responses by clinical area (range 1 to 6)

Legend: Values are overall mean per domain. Statically significant differences:
Domain Information between wards-PICU; Domain Care and Treatment between
wards-PICU and Neonatal Unit- PICU; Domain Organisation between Neonatal Unit-
wards and wards-PICU; Domain Parent participation between Neonatal Unit-PICU;
Domain Professional Attitude between wards-PICU and Neonatal Unit-PICU.