Journal of Pediatric Nursing 63 (2022) 136–142

Contents lists available at ScienceDirect

Journal of Pediatric Nursing

journal homepage: www.pediatricnursing.org

Reliability and validity of home-visit nursing quality indicators for children with medical complexity in Japan

Yumi Sakagami [a,c,*], Naoko Nakayama [b], Kaoru Konishi [c]

[a] Department of Nursing, Osaka Shin-Ai College, Osaka, Japan
[b] Department of Nursing, Kanagawa University of Human Services, Kanagawa, Japan
[c] Graduate School of Medicine, Osaka University, Osaka, Japan

ARTICLE INFO

Article history:
Received 30 August 2021
Revised 14 November 2021
Accepted 27 November 2021

Keywords:
Home-visit nursing
Quality indicators
Children with medical complexity

ABSTRACT

Purpose: This study aims to examine the reliability and validity of Home-visit Nursing Quality Indicators for Children (HNQIC) with medical complexity in Japan that will enable measuring the quality of services provided by home-visit nursing agencies (HNA) for children with medical complexity (CMC) and their families.
Design and methods: This study employed a model that measures medical quality as proposed by Donabedian in a conceptual framework. The HNQIC is comprised of a total of 42 items with responses in 5-point Likert scale: 8 items in "Structure", 24 items in "Process", and 10 items in "Outcome". A self-rating questionnaire survey was administered and responses from 57 home-visit nursing agencies were analyzed. An exploratory factor analysis was performed to examine the validity of the construct, and a covariance structure analysis was performed to examine the structural validity of the model that measures medical quality.
Results: The "Structure" and "Process" sections included 28 items in 5 factors, and the "Outcome" section included 7 items in 3 factors. The Cronbach's α coefficient for all of the items of "Structure" and "Process" was 0.93, and that of "Outcome" was 0.76. As a result of a covariance structure analysis, we obtained following goodness-of-fit indices: $\chi 2 / df = 1.41$, GFI = .897, AGFI = .794, CFI = .926, and for the coefficient of determination $.14 \leq R2 \leq .68$.
Conclusions: As the statistical validity of the HNQIC was confirmed, we determined the goodness-of-fit indices of the model to be acceptable.
Practice implications: The findings suggested that the HNQIC can be used as a quality indicator to access care effects objectively to provide better support.

Introduction

With the development of pediatric medicine and medical equipment over the latest decades, the number of children with medical complexity (CMC) has increased (Foster, Agrawal, & Davis, 2019). In Japan, there are 19,712 CMC patients aged 0 to 19 years living in their communities (unhospitalized), and this number has doubled since 2005 (Ministry of Health, Labour and Welfare, 2020a, 2020b). A previous study reported that CMC have multiple coexisting service needs, chronic conditions, functional limitations, and need for frequent health-care use, and are a subgroup of children which requires a comprehensive and wide range of medical, psycho-social, educational and support services from many agencies and programs (Matsuzawa et al., 2020; Cohen et al., 2012) also reported that CMC assigned patients frequently require intensive use of multiple services (Cohen et al., 2012).

Home-visit nursing that supports CMC from life maintenance and medical care needs plays important roles in the home health care for the afflicted children. However, due to a shortage of nurses involved in home-visit nursing (Carolyn et al., 2019), quality home-visit nursing for CMC patients and their families has not been provided (Nageswaran & Golden, 2017). There are 11,580 home-visit nursing agencies in Japan (Ministry of Health, Labour and Welfare, 2019). However, less than half (43.6%) can support CMC and their families (Sawaguchi et al., 2019), and there are also regional disparities (Nishi et al., 2015). Previous reports have stated that poor-quality home healthcare has negative consequences for CMC and contributes to the caregiver burden (Nageswaran & Golden, 2017), and that accessible, high-quality home health care has the potential to improve health-outcomes in a patient- and family-centered situation and reduce the need for emergency and hospital care (Carolyn et al., 2019). Providing high-quality support to CMC and their families needs home-visit nursing quality indicators as guidelines for nurses performing the support roles.

The Donabedian structure-process-outcome (SPO) model has been widely adopted to develop medical and nursing quality indicators

* Corresponding author at: Osaka Shin-Ai College, 2-7-30, Furuichi, Joto-ku, Osaka, Japan.
E-mail address: ysakagami@osaka-shinai.ac.jp (Y. Sakagami).

https://doi.org/10.1016/j.pedn.2021.11.027
0882-5963/

(Donabedian, 1969). Other developed countries mainly in Europe and the United States have attached importance to medical and nursing quality indicators, and various types of home care quality indicators (HCQI) have been developed. In the United States, outcome assessments based on the Outcome and Assessment Information Set (OASIS), an outcome measure used in Medicare and Medicaid home health care, has been mandatory since 1999, illustrating the importance of outcome-oriented tools to assess quality in the United States (Robert, 2009). In Japan, when the quality of medical and nursing care is measured, the focus is on structure and process rather than on the outcomes of the care (Kita & Itou, 2007). However, outcomes need to focus on specific processes and the relationship between processes and outcomes needs to be analyzed (Wojner, 2001/2003). To establish evidence-based care plans require a multifaceted evaluation based on the SPO model including outcome measures.

The HCQI developed based on the SPO framework in Japan includes a home care quality assessment index (HCQAI) (Arai et al., 2005), which evaluates the quality of home care for older people, and the Quality Indicators of Home Healthcare Nursing for Older Adults (National Association for Visiting Nurse Service, 2019). In European countries, HCQI using the SPO model is also recommended for long-term care (Dondi & Casanova, 2012). However, all HCQI measure quality based on older people and are not necessarily suited to CMC. To improve on this, the present study aims to develop a tool for Home-visit Nursing Quality Indicators for Children (HNQIC) with medical complexity based on the conceptual framework of SPO, and aims to examine the reliability and validity of this HNQIC to provide improvements in the support for CMC and their families.

The level of pediatric medical care index in Japan scores highly among developed countries, and the neonatal mortality rate of Japan is lower than in Europe and the United States (World Health Organization, 2018). However, there may be an increase in the number of CMC patients living in the community in the future. With the development of an HNQIC it will become possible to measure the outcomes of home-visit nursing care objectively, and it will be possible for other countries to provide quality home-visit nursing to CMC and their families in situations similar to Japan. Further, because self-assessment using the HNQIC enables Home-visit Nursing Agencies (HNA) to identify problems in their work and improve their services, it will be useful to improve the quality of HNA.

Methods

Draft Home-visit Nursing Quality Indicators for Children with medical complexity (HNQIC)

This study employed the SPO model of Donabedian as the conceptual framework. Referring to a framework of the guidelines using the SPO model (National Association for Visiting Nurse Service, 2019), question items for "Structure" and "Process" were created. "Outcome" is changes in the mental and physical health and living conditions that occur between two or more timepoints (Shimanouchi, 2018). In this study, we define "Outcome" as "changes in physical, psychological and social conditions of the CMC and their families during the one year from the previous year", and created question items for "Outcome".

To confirm the content validity of the HNQIC items, we administered a questionnaire survey to 22 managing leader nurses of HNA that have taken the initiative to provide home-visit nursing for children, and examined the question items by the Delphi method. As a result, we developed 38 question items: 8 items related to 'Developing the basics for operating the HNA' in "Structure"; 10 items related to 'Specialized services' and 9 items related to 'Interprofessional collaboration' in "Process"; and 3 items related to 'Participation in community development' and 8 items in 'Outcome' (Sakagami et al., 2021). Finally, a pioneering practitioner of pediatric home-visit nursing and three researchers of home-visit nursing science examined these question items, and added two items to 'Process' and two items to 'Outcome', making it a total of 42 items in the draft scale.

Study participants and survey methods

Study participants were managing leader nurses of Home-visit Nursing Agencies (HNA) that provide support to CMC and their families in Japan. We recruited participants by sending return paid post-cards to 2,685 HNA nationwide. We selected agencies that stated their services as "for children" on the website of the Prefectural Home-visit Nursing Association, and agencies that have provided services for children and adolescents under 20 years of age registered in the Nursing Care Service Information Disclosure System of the Ministry of Health, Labour and Welfare of Japan (Ministry of Health, Labour and Welfare, 2016). In total we obtained cooperation from 110 HNA, and sent these a letter that detailed the study outline and ethical considerations, with questionnaires, and return envelopes to the managing leader nurses of the HNA, asking potential participants to return completed questionnaires directly to the researchers. The survey period was between August to December of 2019.

Survey items

Survey items include demographics: year the HNA was established, type of organization, length of time providing pediatric home-visit nursing, registration in national health insurance system as an agency providing 24-hour services, provision for a function-enhanced home-visit nursing care fee, fees for long durations of home-visit nursing care, annexed facilities, number of pediatric users under 18 years old, number of full-time nursing staff, number of nursing staff with experience in pediatric nursing. The 32 items in the "Structure" and "Process" of the HNQIC were measured by 5-point scales, from "Definitely yes (5 points)" to "Definitely no (1 point)". For the 10 "Outcome" items, changes in the conditions of CMC and their families were measured by 5-point scales, "Improved (5 points)" to "Worsened (1 point)" compared to the previous year.

Analysis

Item analysis

We analyzed the distribution of the answers, ceiling and floor effects by mean / standard deviation, Item-Total Correlation (I-T correlation), Corrected Item-Total Correlation, Good-Poor analysis (GP analysis). The exclusion criteria of items for the exploratory factor analysis were items with no significant differences: $r < 0.4$ in I-T Correlation, $r < 0.2$ in Corrected Item-Total Correlations (Polit & Beck, 2008/2010), and items with no significant differences between the lower and higher scoring groups in the GP analysis.

Determination of validity

Prior to the exploratory factor analysis, we performed the Kaiser-Meyer-Olkin test and Bartlett's sphericity test to measure the sampling adequacy. For the sampling adequacy of the 31 items in the "Structure" and "Process" sections, the analysis showed that the KMO was 0.725, BS was X2 ($df = 378$) = 157.116, and $p = .000$. For the sampling adequacy of the 9 items in "Outcome", the analysis showed that the KMO was 0.638, BS was X2 ($df = 21$) = 162.62, and $p = .000$. Sampling adequacy prior to the exploratory factor analysis is considered to be statistically acceptable (Kaiser & Rice, 1974). For the validity of the construct, we performed an exploratory factor analysis by unweighted least squares (promax rotation). As "Outcome" is a qualitative evaluation index (quality indicator) to measure changes over the year, we performed this exploratory factor analysis separately from the "Structure" and "Process" analysis. In the exploratory factor analysis, items with a commonality of 0.16 or more and a factor loading of less than 0.40 were deleted (Oshio, 2019). To examine the external structural validity, we

examined the causal model among conceptual variables by performing a covariance structure analysis because we used the conceptual framework of the SPO model. For the model fit indices, we used chi square (CMIN), goodness-of-fit index (GFI), adjusted goodness- fit index (AGFI), the comparative fit index (CFI), and the root mean square error of approximation (RMSEM).

Determination of reliability

We calculated Cronbach's alpha for the entire scale and subscale factors to examine the internal validity, and used SPSS Statistics Version24.0J and Amos25.0J for the statistical analysis. The statistical significance level was set to 5%.

Ethics

In the letter requesting participation in the study, we explained that the participation and withdrawal are entirely voluntary, that refusal to participate will not result in any disadvantage, that participants can discontinue the cooperation anytime even after consenting to the participation, that anonymity is assured in the publication of the study results, and that adding a check in the check box at the beginning of the questionnaire will be regarded as consent to the participation. This study was conducted with approval of the institution Review Board of the University.

Results

Respondent characteristics

In total 64 home-visit nursing agencies (HNA) (54.5%) responded. Of these 57 responses that had answered all items were determined as valid (51.8%) and were included in the further analysis (Table 1).

Table 1
Characteristics of home-visit nursing agencies.

Characteristic	Finding (n = 57)
	n (%)
Type of corporation	
Medical corporation	8 (14.0)
For-profit corporations	25 (43.9)
Incorporated association/General incorporated foundation	11 (19.3)
Social welfare corporations	7 (12.3)
Other	6 (10.5)
Operating year	
<10 years	32 (56.1)
≥10 years	23 (40.4)
No answer	2 (3.5)
Operating year of pediatric nursing	
<5 years	28 (49.1)
≥5 years	29 (50.9)
Providing 24-hour emergency services covered by the national health insurance system	
Yes	55 (96.5)
No	2 (3.5)
Providing function-enhanced home-visit nursing care covered by the national health insurance system	
Yes	15 (21.1)
No	45 (78.9)
Providing longer hour (≥ 90 minutes) home-visit nursing care as covered by the national health insurance system	
Yes	32 (56.1)
No	25 (43.9)
Nurses - converted as full-time workers	
<7 nurses	35 (61.4)
≥7 nurses	21 (36.8)
No answer	1 (1.8)
Number of patients	
Pediatric patients (<18 years old)	
<4 children	24 (42.1)
≥4 children	31 (54.4)
No answer	2 (3.5)
Medical care insurance (average)	32.3 (SD 21.6)
Long-term care insurance (average)	51.6 (SD 39.0)

Item analysis of Home-visit Nursing Quality Indicators for Children with medical complexity (HNQIC)

The mean values of the items were from 2.61 to 4.33, and 'Changes in the number of families who can respond to matters in the event of emergencies and disasters' in "Outcome" had an I-T correlation of $r < 0.4$; and 'Creation and dissemination of guidelines' in "Process" and 'Changes in the number of families who can respond to matters in the event of emergencies and disasters' in "Outcome" had corrected item-total correlations of $r < 0.2$. For the G-P, there were statistically significant differences in all items. The above two items were deleted from the further analysis as a result of the item analysis.

Determination of validity

Exploratory factor analysis

The number of factors in the exploratory factor analysis was determined to be 5 based on the initial change in eigenvalues and the screen plot. As a result, the "Structure" and "Process" sections included 28 items in 5 factors: <Creation of manuals for a safe care> (4 items) and <Home visit schemes by home-visit nursing agencies (HNA)> (2 items) in "Structure"; <Support of growth and development> (12 items), <Interprofessional cooperation> (7 items) and <Cooperation with other hospitals and home care transition support> (2 items) in "Process" (Table 2).

The number of factors in the exploratory factor analysis was determined to be 3 based on the initial change in eigenvalues and the screen plot. As a result, "Outcome" included 7 items in 3 factors: <Changes in family lifestyle> (2 items), <Changes in care skills of families> (2 items), and <Continuing stable home lives> (3 items) (Table 3).

Covariance structure analysis

A covariance structure analysis was performed to examine the construct validity of the HNQIC. The resulting goodness-of-fit indices were as follows: CMIN = 25.401, (df = 18), $p = .114$, GFI = 0.897, AGFI = 0.794, CFI = 0.926, and RMSEA = 0.086 (Fig. 1).

Determination of reliability

The Cronbach's α coefficient for all of the evaluation indices of "Structure" and "Process" was 0.93, and the coefficients for the first to fifth factors were 0.79 to 0.92. The Cronbach's α confidence coefficient for the whole of the "Outcome" was 0.76, and the coefficients for the first to third factors were 0.69 to 0.82 (Table 4).

Discussion

The average number of full-time nursing staff at the Home-visit Nursing Agencies (HNA) in the present study is equivalent to the national average of 7.1. Further, 80% of the nursing staff have experience in pediatric nursing and there are more pediatric patients under the age of 18 than the national average of 3.1 (Ministry of Health, Labour and Welfare, 2016). The characteristics, as described above are those for HNA actively engaged in home-visit nursing for children.

Representativeness of the sample data

The response rate in the present study was 54.5%, higher than in previous studies that investigated home-visit nursing agencies (HNA) for

Table 2
Exploratory factor analysis for the sample in the "Structure" and "Process" sections.

Contents		Communality	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Factor 1: Support of growth and development							
Process	Assessment of child-specific symptoms and nursing practice	0.63	0.93	−0.21	−0.09	−0.04	0.18
	Advice for the family about health and medical care	0.58	0.81	0.05	−0.17	−0.03	0.07
	Comprehensive assessment and nursing practice	0.58	0.81	−0.06	−0.14	−0.04	0.28
	Advice for the family about childcare and daily life	0.55	0.67	0.26	−0.18	−0.09	0.04
	Support for decision making about home life and treatment	0.60	0.66	−0.20	−0.04	0.37	−0.16
	Respite care for the family	0.54	0.60	0.17	−0.19	0.01	0.36
	Support for parenting and social participation	0.74	0.59	−0.04	0.18	0.29	−0.12
	Advice of managers and leaders about nursing care	0.71	0.54	0.04	0.32	0.13	−0.05
	Nursing practice to promote growth and development	0.65	0.51	0.14	0.18	0.16	0.11
	Advice for the family in cases of emergency and disaster	0.49	0.47	0.01	0.35	−0.15	−0.18
	Information sharing and cooperation when participating in service coordination meetings	0.46	0.47	0.21	−0.05	0.13	0.12
	Nursing practice for the development of sensory integration	0.55	0.47	0.13	0.12	0.19	0.14
Factor 2: Interprofessional cooperation							
Process	Participation in meetings and workshops where different professions are present	0.73	−0.30	0.86	0.04	0.25	0.07
	Participation in conferences related to building interprofessional collaboration schemes	0.56	−0.14	0.66	0.02	0.26	−0.01
	Consultation and home visits accompanied with home-visit nursing agencies specializing in pediatrics	0.40	0.05	0.65	−0.03	−0.10	0.06
	Information sharing and cooperation with related organizations depending on the developmental stage	0.79	0.30	0.59	0.04	0.02	−0.22
	Information sharing and cooperation with kindergartens, schools, and day service agencies	0.75	0.26	0.59	0.26	−0.34	−0.23
	Information sharing and cooperation with social workers	0.55	0.24	0.55	−0.20	0.14	0.15
	Providing information about the conditions and issues of the community	0.49	−0.01	0.51	−0.03	0.30	−0.12
Factor 3: Creation of manuals for a safe care							
Structure	Preparation and dissemination of medical device manuals	0.67	−0.31	−0.03	0.88	0.16	0.25
	Preparation and dissemination of nursing care manuals	0.53	−0.26	0.00	0.81	0.05	0.13
	Preparation and dissemination of manuals for infectious diseases	0.52	0.04	0.14	0.73	−0.23	0.23
	Preparation and dissemination of manuals for emergency or disaster events	0.53	0.37	−0.22	0.52	0.08	−0.09
Factor 4: Cooperation with other hospitals and home care transition support							
Process	Support for the transition to home living (before discharge conference)	0.62	−0.05	0.11	0.10	0.71	−0.05
	Information sharing and collaboration with physicians and caseworkers at core hospitals	0.73	0.28	0.03	0.02	0.66	−0.05
	Support for the transition to home life (out-of-hospital trial)	0.49	0.05	0.16	−0.10	0.62	0.02
Factor 5: Home visit schemes by home-visit nursing agencies (HNA)							
Structure	Home-visit care schemes according to changes in conditions	0.74	0.15	−0.01	0.32	0.00	0.83
	Home-visit care schemes tailored to lifestyles and needs	0.57	0.30	−0.03	0.16	−0.10	0.71
Eigenvalue			10.27	2.17	2.02	1.34	0.99
Explained variance (%)			36.68	7.25	7.74	4.78	3.55
Cumulative (%)			36.68	43.93	36.19	40.97	44.52

Exploratory factor analysis by unweighted least squares (promax rotation).

children in Japan where the response rates were reported as 31.5–45.1% (Nishi & Hakamada-Taguchi, 2020; Otsuki et al., 2020; Sawaguchi et al., 2019). We recruited participants focusing on agencies that stated their services were "for children" on the website of the Prefectural Home-visit Nursing Association, but there are many agencies that do not provide services for children. Otsuki et al. estimated the number of agencies as 1,396 to 1,712 in Japan (Otsuki et al., 2020). As a complete survey of the participating HNA, validity and meaningfulness are ensured, and it is deemed that the sample data represents the actual situation to some degree.

Reliability and validity of the HNQIC

The exploratory factor analysis published elsewhere showed acceptable results as follows: quality indicators of "Structure" and "Process" are comprised of 28 items in 5 factors with a cumulative contribution

Table 3
Exploratory factor analysis for the sample in the "Outcome" section.

	Communality	Factor 1	Factor 2	Factor 3
Factor 1: Changes in family lifestyle				
Changes in the number of families who can find time to go out and rest	0.72	0.88	0.01	−0.06
Changes in the number of families who can spare the time for siblings in the family	0.70	0.83	0.14	−0.14
Factor 2: Changes in care skills of families				
Changes in the number of families who can respond to medical care problems	1.00	−0.02	0.98	0.12
Changes in the number of families who can evaluate and respond to the situations of children	0.47	0.14	0.64	−0.13
Factor 3: Continuing stable home lives				
Length of the home care period of the children	0.88	0.34	−0.20	0.78
Changes in the number of children with stable physical conditions	0.31	−0.29	−0.01	0.64
Changes in opportunities to collaborate with different professionals	0.55	0.02	0.26	0.62
Eigenvalue		2.86	1.10	0.68
Explained variance (%)		40.92	15.76	9.75
Cumulative (%)		40.92	56.68	66.43

Exploratory factor analysis by unweighted least squares (promax rotation).

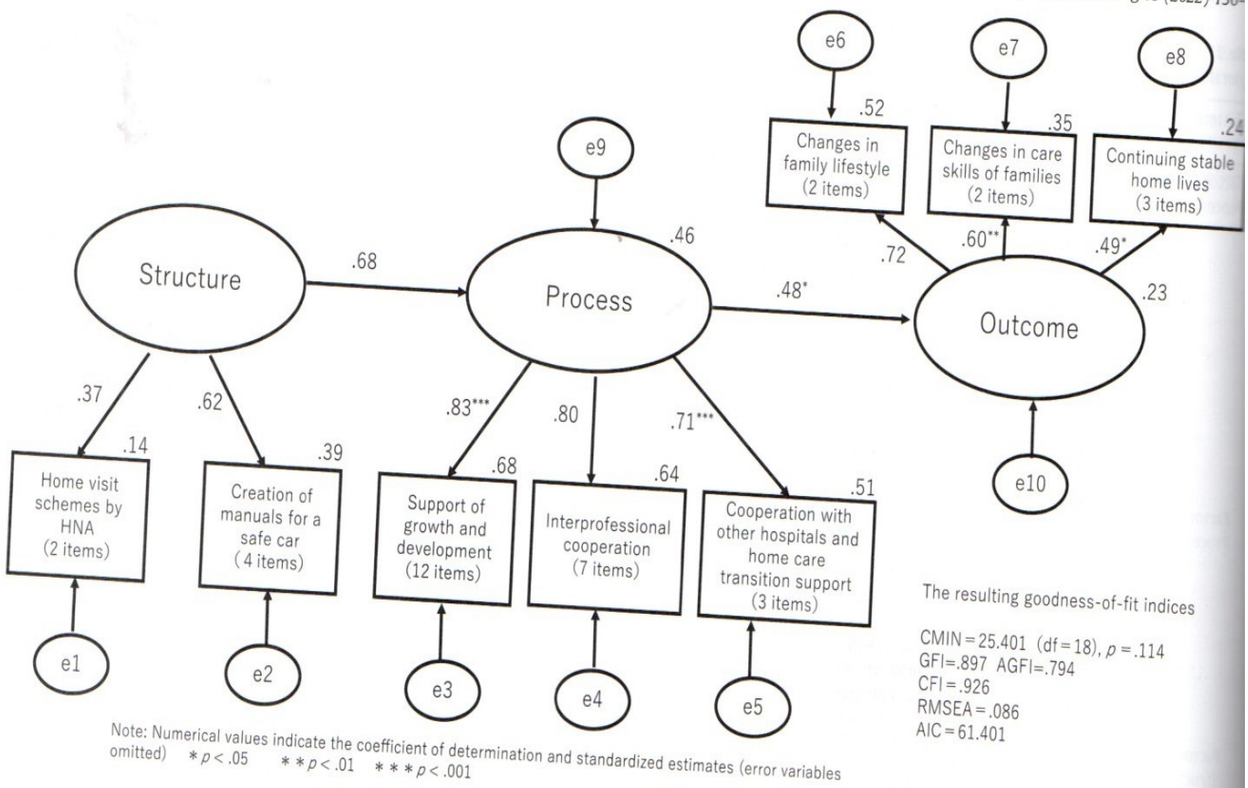

Fig. 1. SPO model of Home-visit Nursing Quality Indicators for Children with medical complexity.

rate of 60%; and "Outcome" is comprised of 7 items in 3 factors with a cumulative contribution rate of 66.4% (Oshio, 2019). For the goodness-of-fit indices by the covariance structure analysis, GFI and AGFI were lower than the standard 0.9 or higher, and RMSEA was slightly higher than the standard 0.05 or below (Oshio, 2019). From the above, the goodness of fit of the model is not excellent, but it may be considered to be within the statistically acceptable range, and the model of this study can also be considered to display construct validity. In the examination of the reliability, a previous study has reported that the minimum allowable range of the Cronbach's alpha coefficient is 0.65 to 0.7 (Develles, 2003). As the entire and subordinate evaluation indices of the present study satisfied this criterion, it is considered that the internal consistency is high. Based on the above, the HNQIC is considered to be an evaluation index that has some degree of validity and reliability.

Table 4
Reliability.

Domains	Cronbach's α
"Structure" and "Process" sections	
Total	0.93
Support of growth and development (12 items)	0.92
Interprofessional cooperation (7 items)	0.87
Creation of manuals for a safe care (4 items)	0.79
Cooperation with other hospitals and home care transition support (3 items)	0.81
Home visit schemes by home-visit nursing agencies (HNA) (2 items)	0.88
"Outcome" sections	
Total	0.76
Changes in family lifestyle (2 items)	0.82
Changes in care skills of families (2 items)	0.81
Continuing stable home lives (2 items)	0.69

Cronbach's α: Cronbach's α coefficient.

Components of the HNQIC

Evaluation indices of "Structure" and "Process"

<Creation of manuals for safe care> is covered by the "Structure" section of the draft scale and includes items related to the manual required for home-visit nurses to provide safe care to children with medical complexity (CMC) and their families. <Home visit schemes by home-visit nursing agencies (HNA)> is also a part of "Structure", and contains items related to the establishment of a scheme for home-visit nursing services suited to changes in lifestyle as required by developmental stages. "Structure" includes facilities, equipment, human resources, and financial resources (Donabedian, 1969), and these are equivalent to the needs of a management plan, personnel management, management/labor control, safety control, and personnel training as it is necessary for the operation of home-visit nursing agencies (HNA) (Japan Visiting Nursing Foundation, 2016). However, the "Structure" of the HNQIC is a component for only the safety control and personnel management, and the results of the covariance structure analysis showed that the explanatory power of <Home visit schemes by home-visit nursing agencies (HNA)> and <Creation of manuals for safe care> is low. This suggests that the items that explain the components of the "Structure" of the HNQIC may not have been sufficiently covered and be in need of further examination.

<Support of growth and development> is comprised of the specialized service items in the "Process" section of the draft scale, and contains items required for home-visit nurses to promote the growth and development of CMC patients and help families perform childcare with a sufficient peace of mind, including in the assessment of health conditions and growth/development of the young CMC patients, nursing care and decision support for CMC and their families (Fleming, 2004), care coordination for families (Suzuki et al., 2017), respite care (occasional relief) for families (Otsuki et al., 2020). <Interprofessional cooperation> is comprised of the items of interprofessional cooperation in the draft of the "Process" section, including the multiple intensive health

care services frequently required by CMC patients, and there is a strong need for care coordination (Altman et al., 2018). It is reported that nurses regularly serve as liaison between different care providers, and in this capacity nurses can ensure that CMC and their families experience a well-integrated coordination of multiple sources of care (Rogers, Reed, Blaine, & Manning, 2021).

<Cooperation with other hospitals and home care transition support> is comprised of items related to support for the transition (transfer) to home care conditions and cooperation with the attending physician of the CMC in the draft of the "Process" section. It is reported that with complex chronic diseases, myriad healthcare needs, and severe limitations on functioning, the transition to the home from the hospital experienced by CMC can be complicated and involve tenuous aspects (Berry et al., 2015). For this reason, transition support is an important component of the HNQIC. As reported, the process measures determine which aspects of home-visit nursing are problematic and thereby translate more readily into recommendations for improving quality, and support items in the "Process" concerns of the HNQIC can be provided as evaluation of the methods and required details of home-visit nursing.

Evaluation indices of the "Outcome" concerns

Shaughnessy, et al. stated that in the Outcome Measure Taxonomy of home care there are three categories: "End-result outcomes (changes in health condition of caretaker)", "Intermediate-result outcomes (changes in caregiver behavior, emotions, and knowledge)", and "Utilization outcomes (use of various health services) (Shaughnessy et al., 1997). <Changes in family lifestyle> in the "Outcome" details are summarized in the daily activities of the family such as when going out, covered in "Intermediate-result outcomes". <Changes in care skills of families> is summarized in the knowledge of the family needed for the medical treatment in "Intermediate-result outcomes". <Continuing stable home lives> is comprised of two elements, "End-result outcomes" and "Utilization outcomes", and is summarized in changes in health conditions of CMC and opportunities for interprofessional collaboration. For CMC to continue home care, family health literacy of children is important (Lawrence et al., 2021), and it may be appropriate as a component of HNQIC outcomes though this explanatory power is somewhat low.

Kita et al. reported that changes in family empowerment as well as physical and mental changes in the caretaker, changes in the sense of burden, and satisfaction experienced by the family caregivers are included in the "Outcome" (Kita & Itou, 2007). In the present study <Changes in family lifestyle> and <Changes in care skills of families> are considered to be important as elements in the "Outcome" necessary for CMC to maintain a stable home care. As described above, the HNQIC is comprised of factors and items supported by previous studies, and is useful as an evaluation index that identifies the issues of home-visit nursing agencies and show the direction for future efforts in elucidating the conditions covered here.

Limitations

The sample of the HNS in the present study is broadly representative. However, there are limitations that the sample size is small. This is due to the data collection methods with the survey conducted in two separate sessions. For the validity, the low goodness of fit of the model may be due to the small sample size. In future studies, we will increase the number sampled and conduct simultaneous analysis of multiple populations to verify the cross-validity. The stability of the indicators was not confirmed because we did not perform a retest this time. For the future, we need to confirm the reliability using the retest method. Items with strong biases and items with low factor loadings were deleted at the stage of the item analysis and the exploratory factor analysis. It is possible that important items may have been excluded due to their low discrimination and distinctiveness. For this reason, to derive items that can be used more generally, it is necessary to examine the reliability and validity while ensuring the sample size and broadening the survey method, and to refine the items that are components of the quality indicators more exhaustively.

Implications for practice

The HNQIC will be useful for managing leader nurses of HNA in managing and operating the organizations that provide support to CMC and their families in Japan. It is also useful as indicators to evaluate the quality and levels of support services provided by home-visit nurses. Because the HNQIC clarifies the functions and roles required for home-visit nursing that supports CMC, it will serve as a guideline for HNA. We expect the HNQIC to contribute to increasing the number of agencies that provide home-visit pediatric nursing as well as it will improve the quality of the services.

Conclusions

The findings suggest that the HNQIC can be used as a quality indicator with which HNA can achieve a care effect objectively to provide better support.

Disclosure

There are no conflicts of interest to declare.

Credit Author statement

Yumi Sakagami: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing - original draft. Naoko Nakayama: Validation, Writing- Reviewing and Editing. Kaoru Konishi: Writing- Reviewing and Editing, Supervision.

Declaration of Competing Interest

There are no conflicts of interest to declare.

Acknowledgements

This study was supported by JSPS KAKENHI Grant Number 17k12383. The authors are grateful for the assistance of the people who participated in this study and the staff who were involved.

References

Altman, L., Zurynski, Y., Breen, C., Hoffmann, T., & Woolfenden, S. (2018). A qualitative study of health care providers' perceptions and experiences of working together to care for children with medical complexity (CMC). *BMC Health Services Research, 18*, 70–111. https://doi.org/10.1186/s12913-018-2857-8.

Arai, Y., Kumamoto, K., Sugiura, M., Washio, M., Miura, H., & Kudo, K. (2005). Development of the home care quality assessment index (HCQAI). *The Japan Geriatrics Society, 42*(4), 432–443 (In Japanese).

Berry, J. G., Hall, M., Cohen, E., O'Neill, M., & Feudtner, C. (2015). Ways to identify children with medical complexity and the importance of why. *The Journal of Pediatrics, 167*(2), 229–237. https://doi.org/10.1016/j.jpeds.2015.04.068.

Cohen, E., Lacombe-Duncan, A., Spaldong, K., MacInnis, J., Nicholas, D., Nrayanan, U., & Friedman, J. N. (2012). Integrated complex care coordination for children with medical complexity: A mixed-methods evaluation of tertiary care-community collaboration. *BMC Health Services Research*, 12. http://www.biomedcentral.com/1472-6963/12/36.

Develles, R. F. (2003). *Scale development: Theory and applications* (2nd ed.). Thousand Osaks, CA: Sage.

Donabedian, A. (1969). Quality of care: problems of measurement. II. Some issue in evaluating the quality of nursing care. *American Journal of Public Health, 59*(10), 1833–1836. https://doi.org/10.2105/ajph.59.10.1833.

Dondi, R., & Casanova, G. (2012). Quality assurance indicators of long-term care in European countries. *ENEPRI research repot, no.110, April 2012.*

Fleming, J. W. (2004). *Home health care for children who are technology dependent.* New York: Springer Publishing.

Foster, C. C., Agrawal, R. K., & Davis, M. M. (2019). Home health care for children with medical complexity: Workforce gaps, policy, and future directions. *Health Affairs, 38* (6), 987–993. https://doi.org/10.1377/hlthaff.2018.05531.

Japan Visiting Nursing Foundation (Ed.). (2016). *New manual for the establishment, operation, and assessment of home-visit nursing agencies* (pp. 163–171) (3rd ed.). Tokyo, Japan: National Association for Visiting Nurse Service Publishing.

Kaiser, H. F., & Rice, J. (1974). Little Jiffy Mark IV. *Educational and Psychological Measurement, 34*, 111–117. https://doi.org/10.1177/001316447403400115.

Kita, M., & Itou, K. (2007). Trends and issues in outcome research for home healthcare support for elderly persons requiring care in Japan. *Journal of Japan Academy of Home Care, 11*(1), 72–77 (In Japanese).

Lawrence, P. R., Feinberg, I., & Spratling, R. (2021). The relationship of parental health literacy to health outcomes of children with medical complexity. *Journal of Pediatric Nursing, 60*, 65–70. https://doi.org/10.1016/j.pedn.2021.02.014.

Matsuzawa, A., Shiroki, Y., Arai, J., & Hirasawa, A. (2020). Care coordination for children with medical complexity in Japan: Caregivers' perspectives. *Child: Care, Health and Development, 46*, 436–444. https://doi.org/10.1111/cch.12767.

Ministry of Health, Labour and Welfare (2016). "Nursing care service information disclosure system" for searches of nursing care service agencies and life related information. https://www.kaigokensaku.mhlw.go.jp/ Accessed on 5 June, 2019.

Ministry of Health, Labour and Welfare (2019). Outline of the 2019 survey of long-term nursing care service facilities and agencies. https://www.zenhokan.or.jp/wp-content/uploads/r3-research.pdf (Accessed on 16 October, 2021).

Ministry of Health, Labour and Welfare (2020a). *Special survey on the verification of results of the medical fee revision in 2016: Survey of implementation conditions in home medical care and home-visit nursing, including a survey of evaluation influence depending on severity and resident status.* https://www.mhlw.go.jp/file/05-Shingikai-12404000-Hokenkyoku-Iryouka/000016634, 3–10 (Accessed on 3 March, 2021).

Ministry of Health, Labour and Welfare (2020b). Trends in support programs for children with medical complexity (CMC). https://www.mhlw.go.jp/content/10800000/000584473.pdf (Accessed on 10 March, 2021).

Nageswaran, S., & Golden, S. L. (2017). Improving the quality of home health care for children with medical complexity. *Academic Pediatric, 17*(6), 665–671. https://doi.org/10.1016/j.acap.2017.04.019.

National Association for Visiting Nurse Service (2019). 2018 Health promotion project for the elderly "Research project for improving the quality of services using ICT in long-term care insurance service providers". *Second edition of self-assessment guidelines for home-visit agencies.* https://www.zenhokan.or.jp/wp-content/uploads/h30-1.pdf (Accessed on 29 March, 2021).

Nishi, R., Enomoto, A., & Taguchi, R. (2015). Supply and demand situation of home-visit nursing station for children requiring medical care at home by prefecture. *Kyoritsu Journal of Nursing, 2*, 33–38 (In Japanese).

Nishi, R., & Hakamada-Taguchi, R. (2020). Actual conditions and related factors in which visiting nurses identify of information provision case might be abused scenes of at-home children with severe motor and intellectual disabilities. *The Journal of Child Health, 79*(1), 36–45.

Oshio, A. (2019). Psychological survey data analysis by SPSS and Amos. *Factor analysis / covariance structure analysis* (pp. 157) (3rd ed.). Tokyo, Japan: Tokyo Tosho Co., Ltd.

Otsuki, N., Fukui, S., & Sakaguchi, Y. (2020). Measuring the benefits of respite care use by children with disabilities and their families. *Journal of Pediatric Nursing, 53*, 14–20. https://doi.org/10.1016/j.pedn.2020.01.016.

Polit, D. F., & Beck, C. T. (2008). *Nursing research principles and laws* (2nd ed.). Tokyo, Japan: Igaku-Shoin, 435–436 (Translated by Kondo, J. (2010). in Japanese).

Robert, J. R. (2009). The history of quality measurement in home health care. *Clinical Geriatrics Medicare, 25*, 121–134. https://doi.org/10.1016/j.cger.2008.11.001.

Rogers, J., Reed, M. P., Blaine, K., & Manning, H. (2021). Children with medical complexity: A concept analysis. *Nursing Forum, 2021*, 1–8. https://doi.org/10.1111/nuf.12559.

Sakagami, Y., Kohira, Y., Shirai, F., & Konishi, K. (2021). Development of indices evaluating quality of care provided by in-home nursing facilities for children with constant medical care. *The Journal of Child Health, 80*(5), 583–593.

Sawaguchi, M., Yamaji, Y., Ota, E., & Tamura, M. (2019). Survey on the use of home-visit nursing care services for children. *Journal of Japan Academy of Home Care, 23*(1), 19–27 (In Japanese).

Shaughnessy, P. W., Crisler, K. S., Schelenker, R. E., & Arnold, A. G. (1997). Outcomes across the care continuum, home health care. *Med Care, 35*(11), NS115–N123 Supplement. https://doi.org/10.1097/00005650-199711001-00013.

Shimanouchi, S. (2018). *Outcome evaluation of home care for use in the field - To improve the quality of the care.* Kyoto, Japan: Minerva Shobo.

Suzuki, S., Sato, I., Emoto, S., & Kamibeppu, K. (2017). Physio-psychological burdens and social restrictions on parents of children with technology dependency are associated with care coordination by nurses. *Journal of Pediatric Nursing, 36*, 124–131. https://doi.org/10.1016/j.pedn.2017.06.006.

Wojner, A. W. (2001). Outcomes management: Applications to clinical practice. *Application of scientific healthcare improvement considerations to clinical practice*, Tokyo (pp. 47–49). Japan: Japanese Nursing Association Publishing Company (Translated by Ibe T and Hayano M (2003): Outcome management).

World Health Organization (2018). *World health statistics*, 25. https://www.who.int/docs/default-source/gho-documents/world-health-statistic-reports/6-june-18108-world-health-statistics-2018.pdf (Accessed on 20 March, 2021).