[2905-HP-QA.174]
Development of a methodology to assess the care burden for the children who require advanced medical care, despite being highly functional

Hirotoshi Maeda, M.D. 1), Izumi Iikura 2), Masahiro Ikari 3), Ikuko Tomomatsu, Ph.D. 4)
1), 2), 3) Medical Incorporated Foundation Harutaka Kai
4) TOMO Lab LLC

Background

1）Neonatal mortality is sharply declining in Japan

・ Neonatal mortality rate (neonatal mortality / 1,000 birth) is sharply declining in Japan.
・ Neonatal mortality rate in 2017 was **0.9** in Japan.

【Reference：Health and Labor Sciences Research Grants：201918009A】

2）Increasing number of the children who need advanced medical care （C-NAMC）in Japan

・ The number of C-NAMC is rapidly increasing in Japan.
・ The number of C-NAMC in 2019 was 20,155人 in Japan. The number was doubled over the past 14 years.
・ As of C-NAMC, especially, the number of children who require ventilator management is increasing. The number was 4,600. It is 17-fold over the past 14 years.

3）2 types of C-NAMC

Bedridden children
Existing concept of severely disabled children

They are conventionally considered as severely disabled.

There are public welfare supports for them. There are also respite facilities, although the number is limited.
When the medical condition is stable, these children do not need complex medical care.

Not-bedridden children

They are not bedridden, or not intellectually disabled, are in the category of new types of disabled children.

Existing public social and welfare system do not cover their supports and expenses.
Even though their medical condition is stable, the requirements for their care are heavy (e.g., These children often remove the ventilator tube by themselves.）
In addition, the number of respite facilities for them is low.

They are conventionally considered as not severe in the level of disability and supports for them are insufficient. The number is rapidly increasing.

4）Time study by caregivers for medical care and care burden

・[EP-110.624], this study NOT prove an increase in care burden with improvement of child's physical ability, which physicians and nurses are empirically feeling.
Motor function was classified into the following three levels: 1) bedridden, 2) not bedridden but unable to stay in sitting position, and 3) not bedridden and able to stay in sitting position).
◆ There were no correlation between the time required for medical care and the level of motor function of patients (* r = - 0.08, p=0.1).
◆ There was a weak negative correlation between the level of care-burden and the level of physical function of patients (* r = -0.2, p=0.19). The care burden tended to reduce as the level of motor function increased.

Figure#1 — Average time (minutes)
Figure#2 — Level of Care Burden
1) bedridden 2) unable to stay in sitting position 3) able to stay in sitting position
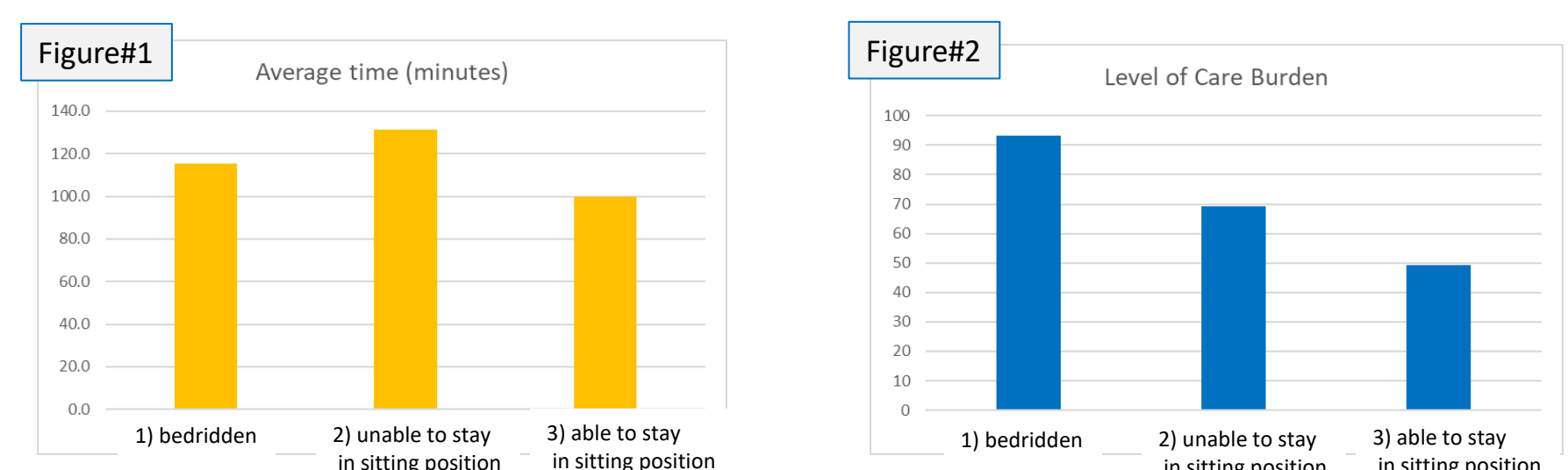
The time-based study using the video data and self-reported questionnaire were not sufficient enough to demonstrate the increasing care burden with the improved child's motor function which are perceived empirically by physicians and nurses.⇒The development of New methods is needed.

Aim/Objective

The purpose of is study is to demonstrate the increased burden on caregivers along with the improvement of child's physical ability, which is known empirically to physicians and nurses.
For this purpose, we developed assessment methods for evaluating the level of "Mimamori: Watching-Over" of which need becomes higher when the motor functions of C-NAMC (Children who Need Advanced Medical Care) improve.

"Mimamori": Watching Over
Both at home and in-facilities, for non-bedridden C-NAMC, the risk of accidents, such as removing tracheal cannula or gastrostomy tube by themselves, becomes higher than bedridden C-NAMC. Therefore, caregivers of such children always need to watch and check the medical devices to prevent accidents from occurring. This task increases the burden for caregivers. Physicians, nurses, and caregivers have empirically known this fact. However, the increase of burden was not demonstrated with objective data. Thus, services to support the burden of Mimamori were not included in the conventional medical welfare system.
Initially, we considered that the burden regarding Mimamori would be quantified by investigating the time and burden needed by primary caregivers at home [No. 1]. However, this method alone was insufficient, except tube feeding (time for medical care and burden increased) and tracheostomy (risk level increased). Therefore, in order to demonstrate the overall correlation between "the improvement of the body function of C-NAMC" and "the level of burden of caregivers," a different approach was necessary.

Methods *chronological flow of data collection

Pilot study: Video data collection　(Max: 24 hours)
・ Data collection period: November, 2018 – January, 2019
・ Participants: 7 participants from 6 families (See the Table#3 of [EP-110.624] for detail)
・ Up to 8 cameras were set for the fixed point observation.
・ Primary caregivers (mostly mothers) filled out care procedures and measured the time.

Quantitative study: Time study by care givers and risk assessment by physicians
・ Data collection period: May, 2019 – February, 2020
・ Survey forms were sent to 1,162 pediatric home-based patients, and 567 caregivers responded.
・ The **time** spent for home medical care was measured by self-reported Time Study.
・ Evaluation of the level of burden felt by main caregivers by questionnaire survey.
・ The **risk** relating to medical care at home were assessed by physicians

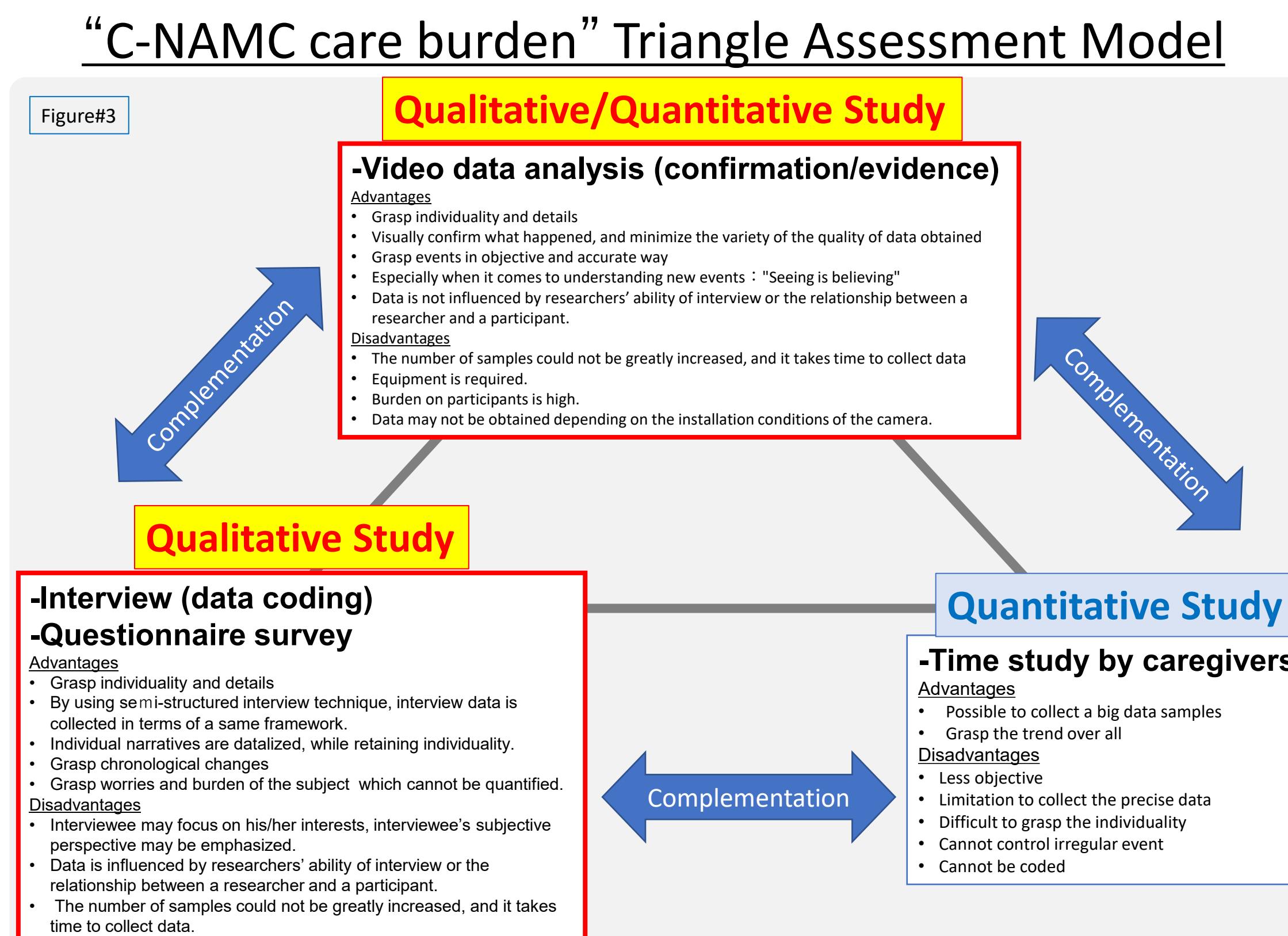**Qualitative study: Interview survey, Video data analysis, Questionnaire survey**
・ Data collection period: November, 2019 – June, 2020
・ Participants: (informed consents were obtained beforehand): Interview: 27 participants from 26 families / Video: 8 participants from 8 families / Web questionnaire: 79 participants
・ Telephone interview / Face-to-face interview
・ Time study by using video recording
・ Questionnaire (participants): caregivers who have experienced cares both of bedridden C-NAMC and non-bedridden C-NAMC)

Results

(1) Developing an assessment model for "Mimamori" by combining quantitative and qualitative studies
● By combining multiple assessment methods, the weaknesses of individual evaluation methods were mutually complemented.
● Qualitatively, we focused on interviews with primary caregivers. The interview data was coded with two axes (medical care x child's behavior). The two-axes coding made it possible to analyze individual medical care separately.
● We found that the burden and risk of each medical device differed.
● The Video data demonstrated the overall picture of the burden of medical care with objective evidences.
(The perfect match between the results of the time of care and the video data provided a major revelation for the system revision.)

"C-NAMC care burden" Triangle Assessment Model

Figure#3

Qualitative/Quantitative Study
-Video data analysis (confirmation/evidence)
Advantages
● Grasp individuality and details
● Visually confirm what happened, and minimize the variety of the quality of data obtained
● Grasp events in objective and accurate way
● Especially when it comes to understanding new events： "Seeing is believing"
● Data is not influenced by researchers' ability of interview or the relationship between a researcher and a participant.
Disadvantages
● The number of samples could not be greatly increased, and it takes time to collect data
● Equipment is required.
● Burden on participants is high.
● Data may not be obtained depending on the installation conditions of the camera.

Qualitative Study
-Interview (data coding)
-Questionnaire survey
Advantages
● Grasp individuality and details
● By using semi-structured interview technique, interview data is collected in terms of a same framework.
● Individual narratives are datalized, while retaining individuality.
● Grasp chronological changes
● Grasp worries and burden of the subject　which cannot be quantified.
Disadvantages
● Interviewee may focus on his/her interests, interviewee's subjective perspective may be emphasized.
● Data is influenced by researchers' ability of interview or the relationship between a researcher and a participant.
● The number of samples could not be greatly increased, and it takes time to collect data.

Quantitative Study
-Time study by caregivers
Advantages
● Possible to collect a big data samples
● Grasp the trend over all
Disadvantages
● Less objective
● Limitation to collect the precise data
● Difficult to grasp the individuality
● Cannot control irregular event
● Cannot be coded

Complementation

2）Interview (data coding)
■Hypothesis based on the tentative analysis of time study, video data and interview data

【H 1】 Caregiver need additional moves, time, and effort to complete medical care caused by child's moves and behaviors
【H 2】 Depending on combinations of C-NAMC's behavioral characteristics and types of medical care, medical risk increases as well as caregiver's burden to prevent risk from occurring or increasing.

Results

■Extract narratives that correspond to the hypothesis and coded in 2 -axis = medical care x child's behavior

○ Narrative of tube feeding
A child with a ventilator often uses nasal tube to be fed with milk. It is difficult to change the tube when the child begins to be active. Recently, it's been difficult even at home. When the child is bedridden, he didn't move much. It was fine, but now, I have to hold him down and hold his face [caregiver's responses]. When the child refuses and resists　[child's behaviors], everything becomes a little difficult. 【code: nutrition injection x refusing/resisting】

○ Narrative of tracheostomy cannula
(When the tracheostomy cannula came out) I was already in a panic [Caregiver's response]: It would be fine if I could put it in immediately after it came out, but it did not go in. I could not get it in, and it gets stuck. The child also started crying. My wife tried to put it in, but it wouldn't go in properly. He could not speak, and could not cry out like a normal child when he is disturbed and wants the attention of parents. He knows that parents come to see him immediately if he tries to pull it (cannula) out [child's behavior]. 【code: tracheostomy cannula x pulling out by himself】

■Medical Care x 2-axis code for each hypothesis

Medical device/ Medical care	Hypo 1 Care burden (additional moves, time, labor)	Hypo 2 Higher risk increases care burden	2 axes codes for Hypo 1	2 axes codes for Hypo 2
tracheostomy cannula	0	6	—	tracheostomy cannula x pull tracheostomy cannula x act violently tracheostomy cannula x pulling out by himself
Ventilator	0	14	—	Ventilator x act violently Ventilator x turning over Ventilator x move hands and arms (remove) Ventilator x move hands and arms (change settings ventilator) Ventilator x walk or stand holding on to things
tube feeding	13	8	nutrition injection x act violently nutrition injection x refusing / resisting nutrition injection x move hands and arms (pulling tubes) nutrition injection x walk	gastrosoma x crawl nutrition injection x turning over ED tube x turning over ED tube x refusing / resisting

Table#1

3）Questionnaire survey: Not-bedridden C-NAMC
Questionnaire (subjects: caregivers who have experienced cares both of bedridden C-NAMC and not-bedridden C-NAMC)

In response to a question about the change in the burden of medical care, **83.2% of the total respondents answered that the level of burden "remained the same" or "became more difficult" after the child became "not-bedridden," compared to when they were bedridden.**

Changes of SSCB — N=79
became easier / remained the same / became more difficult
Tracheostomy, Suction, Ventilator, Drug inhalation, Oxygen, Phlegm Expectorator, Tube Feeding, Peritoneal dialysis, Central venous nutrition, Self-contained urine, PCA, Continuous suction, Airway insertion
Figure#4

N=79
became easier 16.8%
became more difficult 33.8%
remained the same 49.4%
Figure#5

Results

4）A new disability welfare system (new medical care assessment score) was established.
As the reality of "Mimamori: Watching-Over" was revealed, medical care (previously difficult to assess at home and in the community) became assessable. As a result, a new disability welfare system was established. The system starts in April 2021. Specifically, tube feeding, which had been assessed lower as an object of support in the past, was assessed higher. 'Mimamori' score which evaluates the risk level of each medical care were newly set.

Old
Medical Care	Score
Ventilator management	8
Tracheostomy	8
Gastric tube feeding	5
Intestinal tube feeding	8

Table#2
*Extract

"Mimamori" (Watching-Over)

New
Medical Care	Base Score	Risk Assessment by physical ability		
		high	middle	low
Ventilator management	10	2	1	0
Tracheostomy	8	2		0
Gastric tube feeding	8	2		0
Intestinal tube feeding	8	2		0

Table#3
*Extract

● In the new score system, decision is made by the sum of the basic score plus the 'Mimamori' score. A score of 8 or higher is a requirement for additional nursing staff in welfare facilities.
● The 'Mimamori' score is assessed based on the risk level which may cause any accidents/complications due to not-bedridden condition (move hands and arms, turning, crawling and walking), intellectual disabilities (corresponding to below 6 years of age), and behavioral disabilities of C-NAMC.
✓ Not-bedridden condition: move hands and arms, turning, crawling, walking, and walking
✓ Intellectual disabilities: cannot understand what he/she should not do, intellectually less than 6 years old
✓ Behavioral disabilities: cannot behave well
● The basic score for medical care and Mimamori score are assessed based on written opinion of the attending physician.

Discussion

In order to demonstrate the increase in the burden on caregivers along with the improvement of child's physical ability (observed empirically physicians and nurses), it was not enough to conduct a time study asking the primary caregivers about the duration of medical care and subjective sense of care burden of medical care.

The reason for this is that the care burden for a child in medical care is not solely due to medical care. Relieving children to give medical care, and to pay attention and watch (Mimamori) over the child's behaviors and activities, are important in order to eliminate risks arising with medical care.

This kind of "calming the child or constant watching-over burden" was difficult to evaluate using only quantitative survey data. By combining the qualitative approach of interviews, this became possible. In addition, we were able to corroborate the content of interviews by questionnaire survey results and by video data which was collected using multiple cameras installed in households. By combining these data, a more solid evidence has been generated to demonstrate their benefits.

Prior to the coding of interview transcripts, the tentative findings of the video data analysis were referenced to set the following hypotheses:
- Caregiver needs additional moves, time, and effort to complete medical care caused by child's moves and behaviors
- C-NAMC's moves and behaviors increase the risk to complete medical care. By this, caregiver's burden to prevent the risk occurs or increases.

The first coding was done using only keywords expressing the child's moves. No significant results were obtained for the burden and risk of different medical care and medical devices. Then, we reached to 2 axes coding which consists of 'medical care x child's behaviors'. The 2-axes coding demonstrated child's behaviors as cause of the burden of caregivers (by even increasing the burden).

"C-NAMC care burden" Triangle Assessment Model which was developed in this study, has made it possible to reveal the actual situation of 'Mimamori', which had been considered difficult to prove, and its assessment has become possible.

This study has made medical care (traditionally been difficult to evaluate at home and in the community in Japan's disability welfare system) assessable. As a result, a new scheme was established, which is enforced from April 2021. Specifically, tube feeding (assessed lower as an object of support in the past) was highly assessed. "Mimamori" score which evaluates the risk level of each medical care was newly developed.

Conclusion

★This study proved the increase in the burden on caregivers along with the improvement of children's body function which physicians and nurses empirically perceive.
★This study revealed behavioral characteristics of children that increases the burden of caregivers for each medical care.
- Medical device and children's behaviors which impact on the care burden and risk were classified (e.g. "tracheostomy cannula x pulling").
- The classification made it easier to understand the characteristics and risks of each medical care.
- The necessary support for each medical care was clarified.

In summary, we were succeeded in providing the data and rationale for creating a scheme more in line with the actual situation of C-NAMC and their caregivers.

Key References

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