ISO TC210 JWG4
July 24 2023

Risky and Impractical Conditions Brought About by the Full Implementation of ISO 80369-3 Compatible ENFit Connectors

Akiko Nagae

ISO/TC210/JWG4

Biwakogakuen Kusatsu Medical and Welfare center for disabilities
Shiga prefecture, Japan

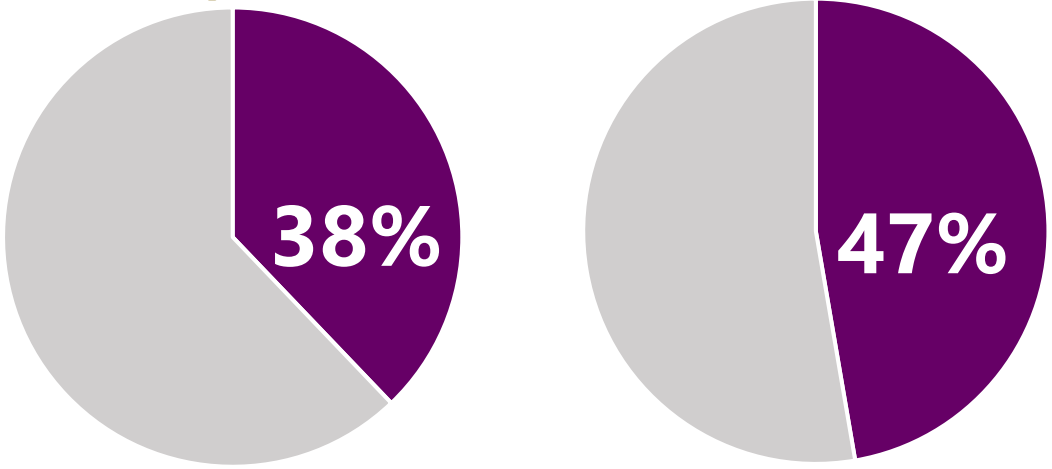
PURPOSE

For the sake of global harmonization, Japan decided to introduce the ISO 80369 series but concluded that in Enteral Nutrition (EN), ISO80369-3(ENFit) should be partially implemented with the conventional type because the conventional devices are necessary from some viewpoints of troublesome conditions.

This presentation reveals the challenges of ENFit and the risky and impractical conditions brought about by the full implementation of ENFit based on research and survey conducted by the Ministry of Health Labor and Welfare (MHLW) research group.

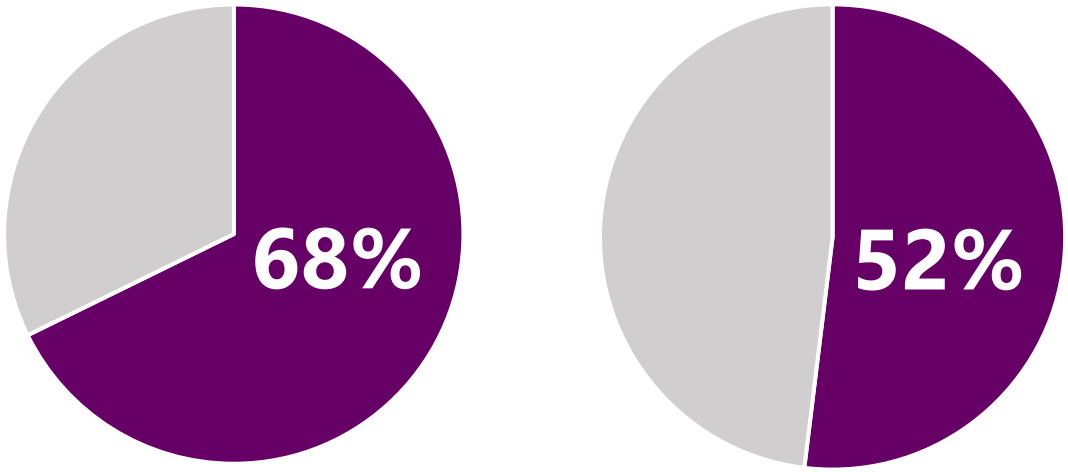
A questionnaire survey conducted during the transition period to ENFit revealed significant differences in the ENFit rate between pediatric and adult fields

Home care
(907 respondents)



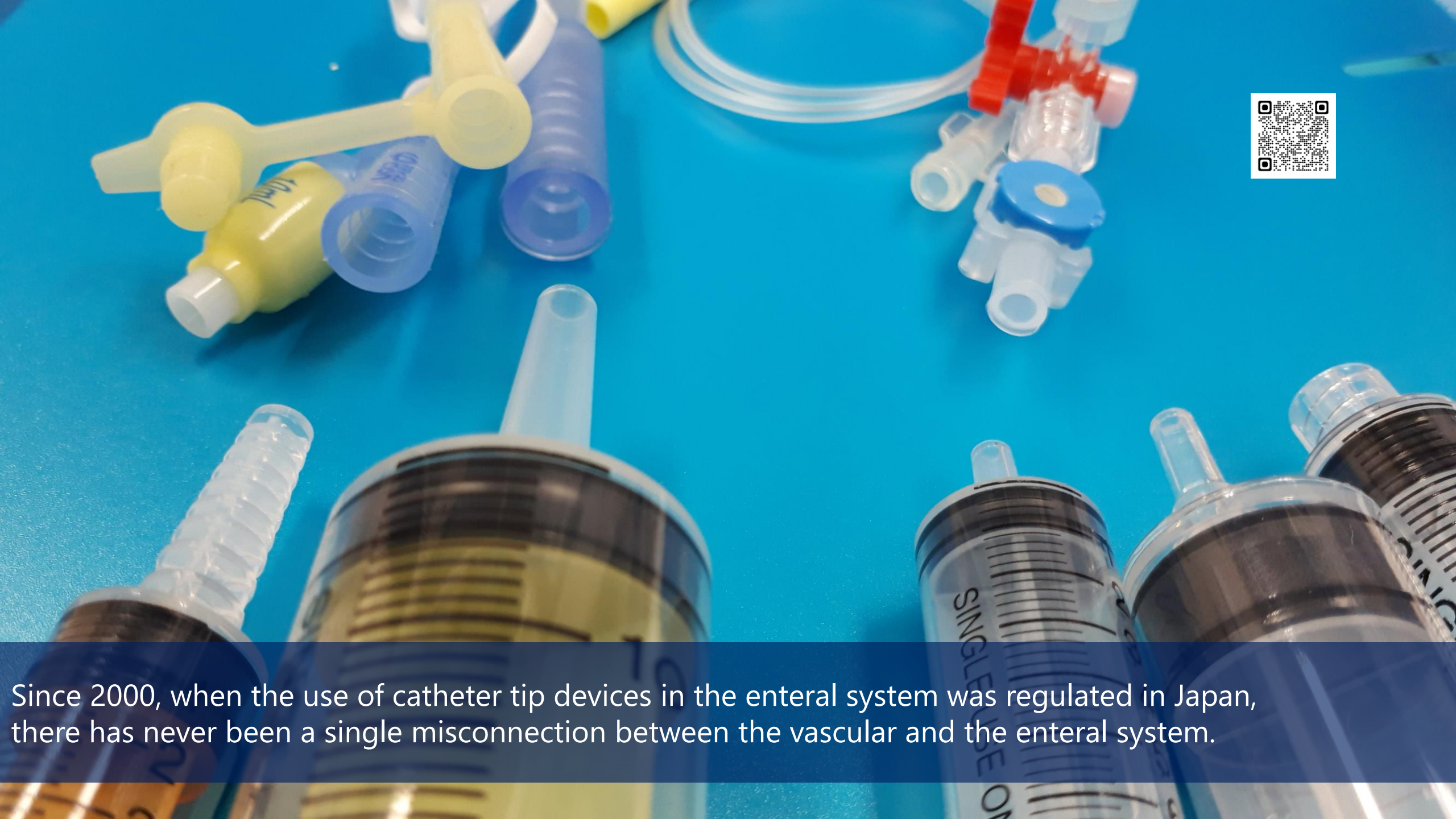
p<0.05

Medical facilities
(435 respondents)



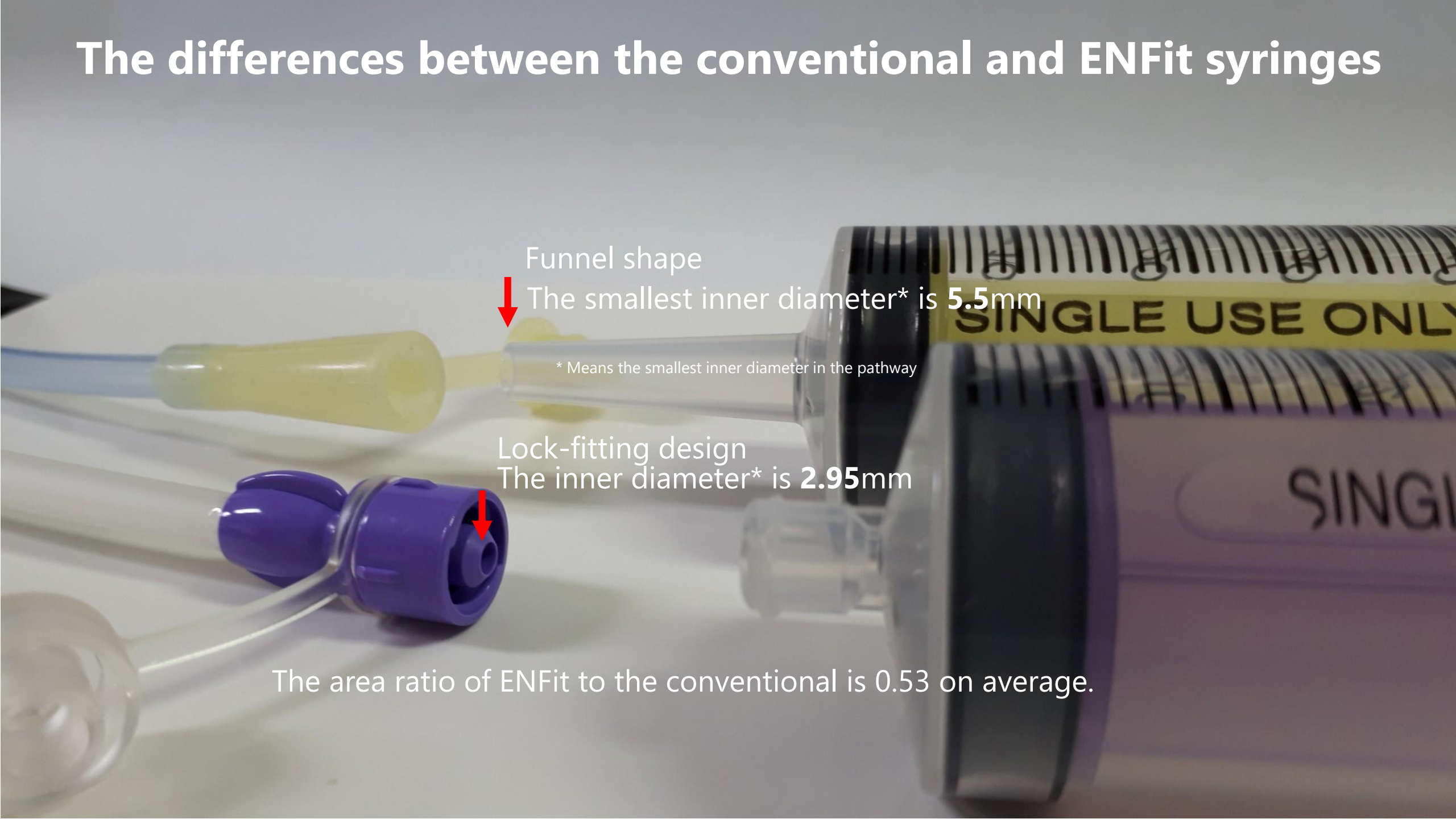
p<0.0001

A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.



Since 2000, when the use of catheter tip devices in the enteral system was regulated in Japan, there has never been a single misconnection between the vascular and the enteral system.

The differences between the conventional and ENFit syringes



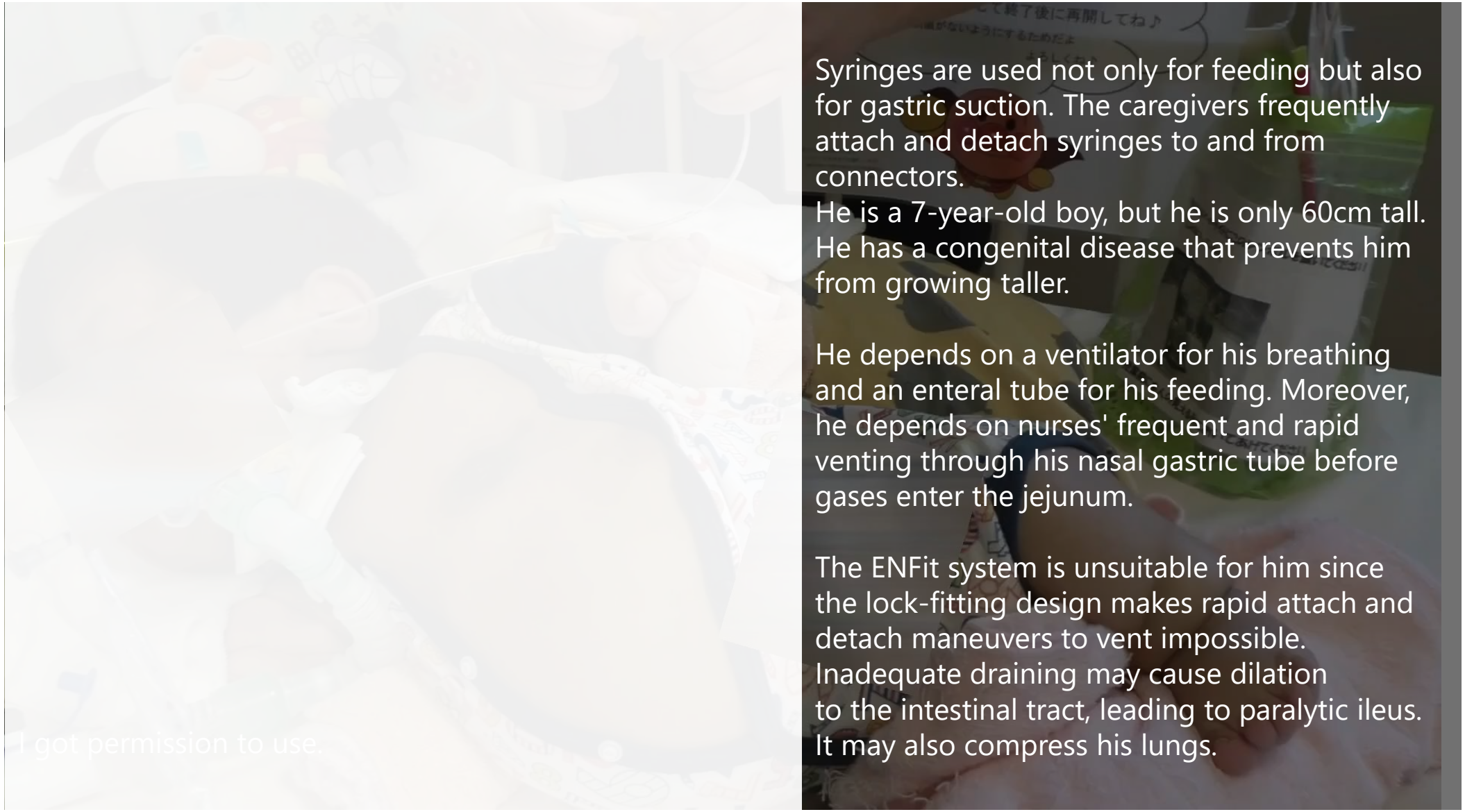
Funnel shape
The smallest inner diameter* is **5.5**mm

* Means the smallest inner diameter in the pathway

Lock-fitting design
The inner diameter* is **2.95**mm

The area ratio of ENFit to the conventional is 0.53 on average.

Caregivers use syringes for gastric suction.



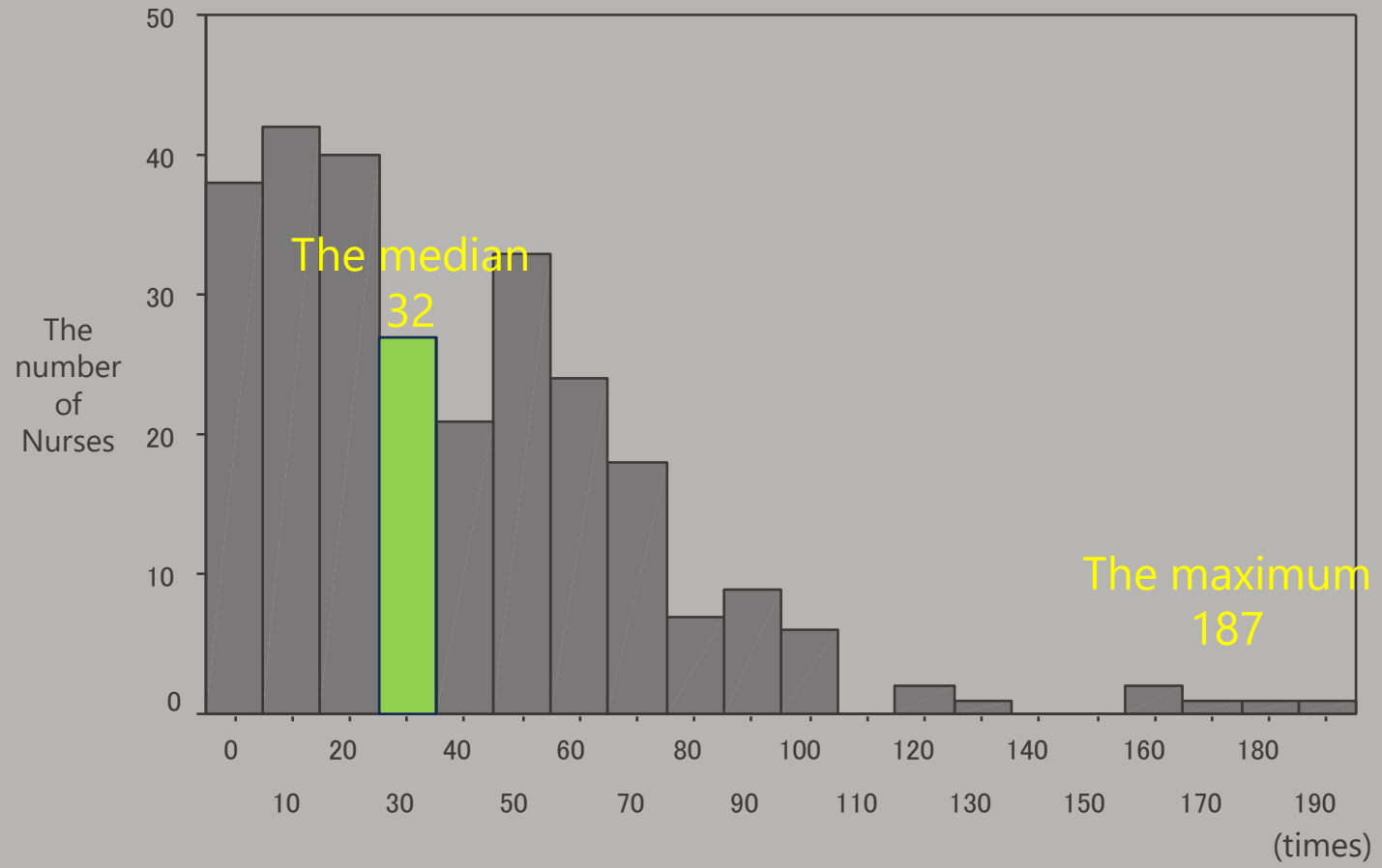
Syringes are used not only for feeding but also for gastric suction. The caregivers frequently attach and detach syringes to and from connectors.
He is a 7-year-old boy, but he is only 60cm tall. He has a congenital disease that prevents him from growing taller.

He depends on a ventilator for his breathing and an enteral tube for his feeding. Moreover, he depends on nurses' frequent and rapid venting through his nasal gastric tube before gases enter the jejunum.

The ENFit system is unsuitable for him since the lock-fitting design makes rapid attach and detach maneuvers to vent impossible. Inadequate draining may cause dilation to the intestinal tract, leading to paralytic ileus. It may also compress his lungs.

I got permission to use.

These are the number of attachment and detachment maneuvers performed by clinicians on an 8-hour working shift at the residential hospitals .
The median and the maximum are 32 and 187 times, respectively.



The number of attachment/detachment maneuvers performed by clinicians during 8 hours

Participants;
140 Clinicians
156 Patients

During the dayshift
At 3 residential hospitals

The number of attachment/detachment actions needed for populations with severe motor and intellectual disabilities. Journal of SMID. 46(1), 2021 Akiko Nagae

Prevention of Future Deaths Reports – Stephen Oakes and Peter Hussey

P 908 views

patient safety learning the hub — an award-winning platform to share learning for patient safety

Home > Learn > Investigations, risk management and legal issues > Investigations and complaints > Coroner reports

PUBLISHED
29 April, 2021

ORIGIN
UK

TYPE
Reports and articles

CONTENT TYPE
Pre-existing

COPYRIGHT STATUS
Original author

PAYWALLED
No

ORIGINAL AUTHOR
Margaret Jones

ORIGINAL PUBLICATION DATE
19/04/21

SUGGESTED AUDIENCE
Health and care staff, Patient safety leads

TAGGED

Coroner reports
Medicine - Gastroenterology
Patient death

Summary

These coroner reports relate to two patients, Stephen and Peter, who both died as a result of complications from use of a nasogastric tube. The coroner notes concerns that this issue may be more widespread and has therefore highlighted the report to several relevant bodies who she advises to take action.

Content

The author of both reports, Margaret Jones HM Assistant Coroner, notes the matters of concern are as follows:

1. The product description used by Enteral was insufficient to enable the end user to clearly identify that the tube marketed as a carefeed size 14FR feeding and drainage tube would not operate as a 14Fr tube due to the restricting en-fit connector.
2. Enteral sales marketing staff were not trained to recognise the new restriction in the bore of the tube and were consequently unable to advise the end user of the change.
3. The Hospital Trust did not fully evaluate the size 14FR tube prior to replacing all previous drainage tubes (Ryles) with the carefeed 14Fr feeding and drainage tube. Feedback was generally difficult to obtain.
4. Nursing staff did not consider alternative action when the NG tubes were not adequately draining. There was no general recognition of the need to aspirate the tube.
5. There is no compulsory training of clinicians required to undertake root cause analysis.
6. Despite reports to the MHRA and issue of amended instructions for use and a field safety notice the product continues to be promoted as suitable to feeding and drainage. Please see link to the Nursing times.
7. This was a joint inquest into the death of two patients who died in quick succession as a result of the Enteral 14F nasosgastric tube being used for decompression in an emergency situation. Four similar (non-fatal) incidents followed. It was not clear to the hospital that the Enteral connector reduced the bore of the size 14Fr tube. The inquest was aware that other Hospital Trusts had also needed to change the tubes. I am concerned that the product labelling problem identified during these inquests may not be limited to the University Hospital North Midlands but is in fact a much wider problem that merits wider industry investigation and changes.

RELATED HUB CONTENT

Lessons from web scraping coroners' Prevention of Future Deaths reports (January 2023) Latest comment by **Patient_Safety_Learning**

Prevention of future deaths report: Alexandra Briess (6 April 2023) Latest comment by **Patient Safety Learning**

Preventing Future Deaths from Medicines: Responses to Coroners' Concerns in England and Wales (8 October 2018) Latest comment by **Patient_Safety_Learning**

There are coroner reports related to two patients who both died as a result of complications from the use of a nasogastric tube which would not operate as a 14Fr tube due to the restricting ENFit connector.

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Enteral (GB) UK** **2. University Hospital Of North Midlands** **3. Nursing Times Publications Editor** **4. NHS England Small Bore Connector Clinical Advisory group (Supply Chain StakeholdersMHRA/NHS Supply Chain/British Standards and Industry Groups)** **5. ISO Standards Agency**
1	**CORONER** I am Margaret J Jones HM Assistant Coroner for Stoke-on-Trent & North Staffordshire Coroner's Court.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 21/12/2017 I commenced an investigation into the death of Peter John Hussey, aged 81, which concluded at the end of the inquest on 19th April 2021. The deceased was diagnosed with mid rectal cancer in 2016. He underwent anterior resection of the bowel with loop ileostomy on the 7th October 2016. He underwent elective reversal of the ileostomy on the 4th December 2017 at the University Hospital North Midlands. On the evening of the 5th December 2017 nursing staff noted he was vomiting. A nasogastric tube was passed at 03.20 hours on the 6th December 2017 but he continued to vomit despite the nasogastric tube being in place. A chest x-ray confirmed aspiration pneumonia and abdominal film reported an evolving adynamic ileus. He was transferred to the intensive care unit but continued to deteriorate and died at 20.00 hours on the 12th December 2017. The following probably contributed to his death:- The use of a nasogastric tube which was unsuitable when used for stomach decompression. A failure to The following possibly contributed to the death :- correct usage of the carefeed 14F nasogastric tube. A failure by the trust to adequately evaluate the nasogastric tube during the procurement process. The 1a. Aspiration pneumonia 2. Chronic obstructive pulmonary disease and pulmonary fibrosis combined. The conclusion of the inquest was: - The deceased died from post-surgical complications which included the use of a carefeed 14F nasogastric tube which inadequately drained the stomach allowing vomiting past the tube leading to aspiration pneumonia and death.
4	**CIRCUMSTANCES OF THE DEATH** See above
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Enteral (GB) UK** **2. University Hospital Of North Midlands** **3. Nursing Times Publications Editor** **4. NHS England Small Bore Connector Clinical Advisory group (Supply Chain Stakeholders MHRA/NHS Supply Chain/British Standards and Industry Groups)** **5. ISO Standards Agency**
1	**CORONER** I am Margaret J Jones HM Assistant Coroner for Stoke-on-Trent & North Staffordshire Coroner's Court.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 11/11/2020 I commenced an investigation into the death of Stephen James Oakes, aged 59. The investigation concluded at the end of the inquest on 19th April 2021. The deceased had suffered with pain in his back and a cough since December 2014. He was seen by a number of doctors but the cause was not identified. In July 2016 he was diagnosed with carcinoma of the lung which had metastasised. On the evening of the 21st December 2017 he was admitted to the University Hospital North Midlands with a history of abdominal pain and vomiting. A CT scan suggested a remediable bowel obstruction due to the metastatic cancer and changes suspicious of existing left lower lobe infection. A nasogastric tube was placed to decompress the stomach. Conservative management was planned for 24 hours to see if the problem resolved, failing which surgery was a consideration. At 06.17 hours on the 23rd December 2017 he deteriorated significantly and was vomiting past the nasogastric tube. A chest film showed changes consistent with aspiration pneumonia. He died at the hospital at 11.30 hours on the 23rd December The following probably contributed to the death:- Miscommunication between Enteral, the manufacturer of the tube and the Hospital trust as to the correct usage of the carefeed 14F nasogastric tube. A failure by the trust to adequately evaluate the nasogastric tube during the procurement process. The cause of death was:- 1a Aspiration pneumonia 1b Small bowel obstruction secondary to metastatic carcinoma 1c Metastatic bronchial carcinoma The conclusion of the inquest was The deceased died from complications caused by the use of a carefeed 14F nasogastric tube which inadequately drained stomach contents allowing vomiting passed the tube leading to aspiration pneumonia on a background of significant natural disease.

Any medical professional knows how difficult it is to prove and report that a patient's death was caused by the restricting ENFit connector. With already two factual reports, it is my utmost hope that we take action to prevent a similar case in Japan. We do not need identical cases such as these before we do something about it. We must act on it.
Now I am an ISO member, I am in charge of this.

Incomplete instructions on ISO 80369-3 for gastric suction

← ICS ← 11 ← 11.040 ← 11.040.25

ISO 80369-3:2016

Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications

Abstract

Preview

ISO 80369-3:2016 specifies the dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections on enteral medical devices and accessories.

NOTE 1 Enteral medical devices include enteral feeding sets, enteral drainage sets, enteral syringes, and patient interface devices including access ports.

It does not specify the dimensions and requirements for the medical devices or accessories that connectors. Such requirements are given in particular International Standards for specific medica or accessories.

It does not specify requirements for small-bore connectors that are used for the following:

- gastric suction-only medical devices;

- oral-only medical devices;

EXAMPLE An oral tip syringe that is not intended to connect to another medical device. It is intended to administer directly to the patient's mouth.

- pressurizing and depressurizing the retention mechanism (e.g. balloon) used to hold invasive enteral medical devices in place;

- medical devices for rectal drainage, rectal administration of medicines or fluid, and any other rectal access medical device;

- gastrointestinal endoscopy equipment;

- skin level gastrostomy medical devices.

NOTE 2 Manufacturers are encouraged to incorporate the small-bore connectors specified in ISO 80369-3 :2016 into enteral medical devices or accessories, even if currently not required by the relevant particular medical device standards. It is expected that when the relevant particular medical device standards are revised, requirements for small-bore connectors, as specified in ISO 80369, will be included.

Buy this standard

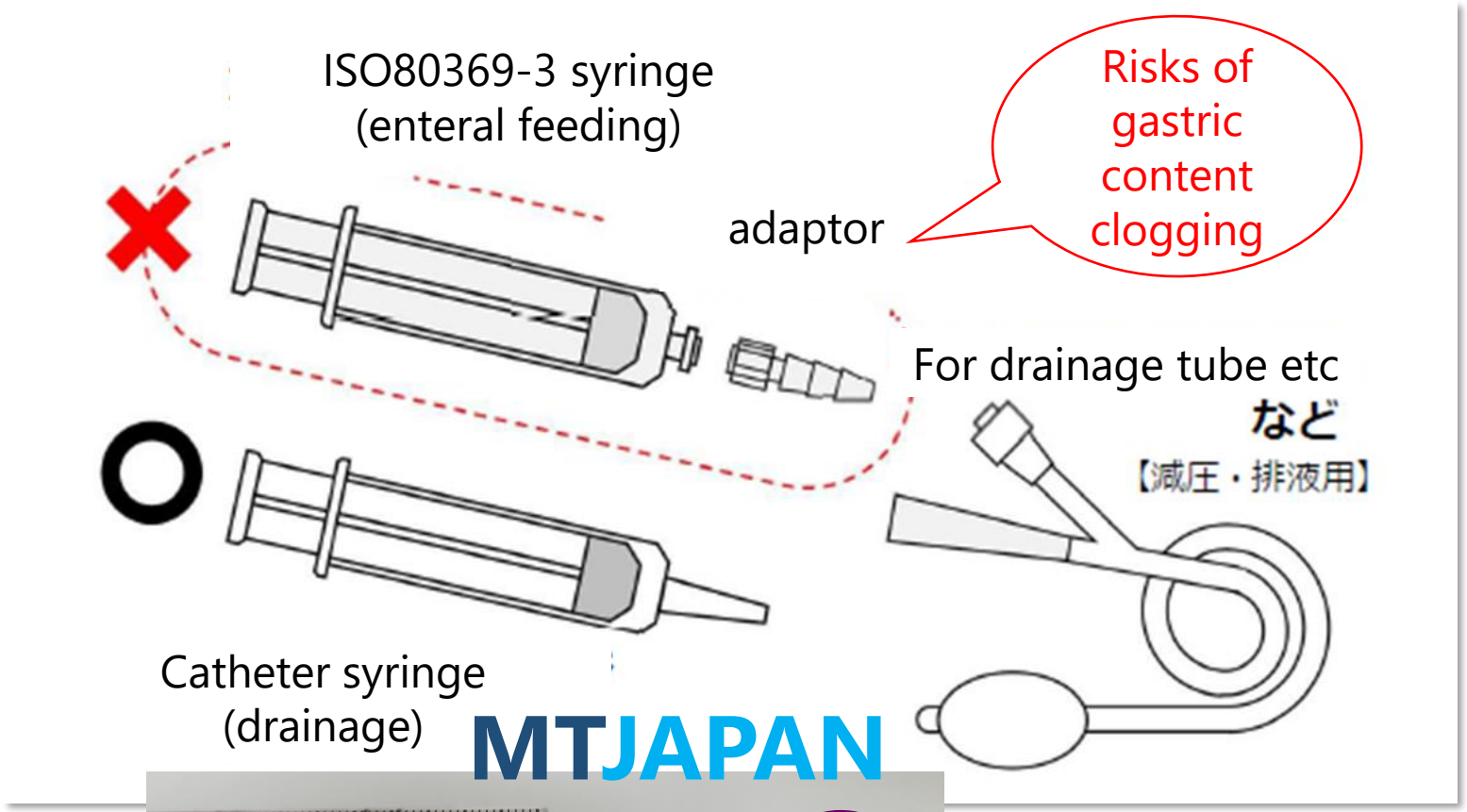
Format	Language
✓ PDF	English

Gastric suction-only medical devices were not specified requirements for small-bore connectors

**However, my patient does not need gastric suction-only medical devices. In fact, his nostrils are too small and that he will not be able to stand having two tubes.
He needs just one tube for both functions: suction and infusion.**

Incomplete instructions on ISO 80369-3 for gastric suction

Representation of gastric suction instructions in Japan



There is no clear instructions !!

However, there is no instructions if we should use only ENFit syringes for gastric suction.

Incomplete instructions on ISO 80369-3 for gastric suction

Enteral-FAQs Ver 7 from the GEDSA website

Home | ENFit | ENFit FAQs | Enteral-FAQs Ver 7

No. Connectors on skin-level feeding devices are out of scope of the new ISO 80369-3 design standards, so those specific device connectors will not change. At the point that extension sets attach to these devices the connection will likely remain the same since those connection points are
extension set (often called th
syringes will have the new EN

28. **Will using a transition con
bolus extension–syringe**

Yes, the hole will likely be sm
won't be smaller than the enc
long as the end of the extens
properties are not expected to change from the cu

29. **Will the new connectors allow for venting?**

Yes. Venting will work in the same manner. Venting a feeding tube with the new standard ENFit connector will require a syringe with the new ENFit connector.

Will the new connectors allow for venting?

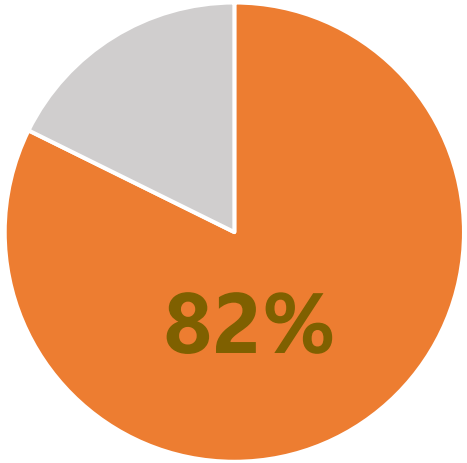
Yes. Venting will work in the same manner. Venting a feeding tube (with the new standard ENFit connector) will require a syringe with the new ENFit connector.

As a medical professional, let me share that based on my experiences and observations, there are some patients who cannot be suctioned or vented adequately with ENFit. Now, let me show you other results of the survey related to gastric suction, which exhibits that ISO 80369-3 specification is insufficient and does not match reality.

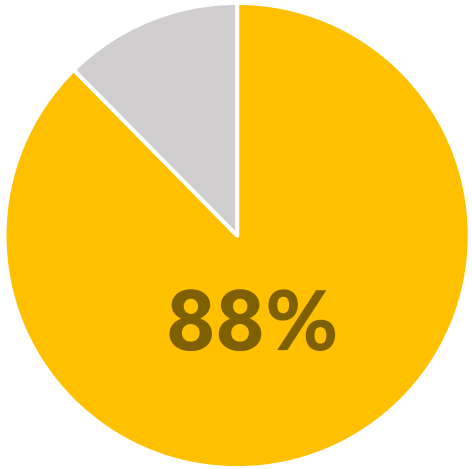
More than 80% of the respondents practice Gastric suction in each department.

Home care
(907 respondents)

Adult
(243 respondents)

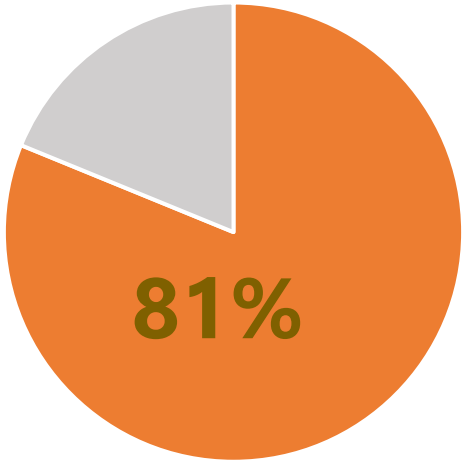


Pediatric
(702 respondents)

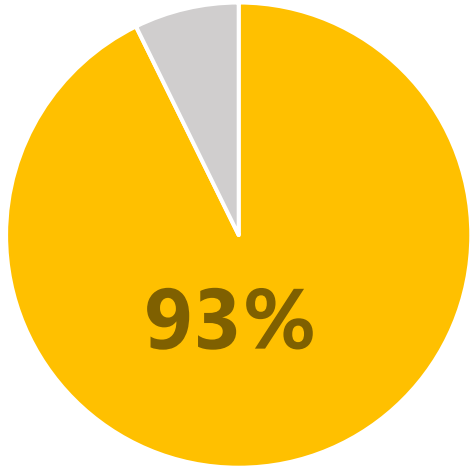


Medical facilities
(435 respondents)

Adult
(186 respondents)



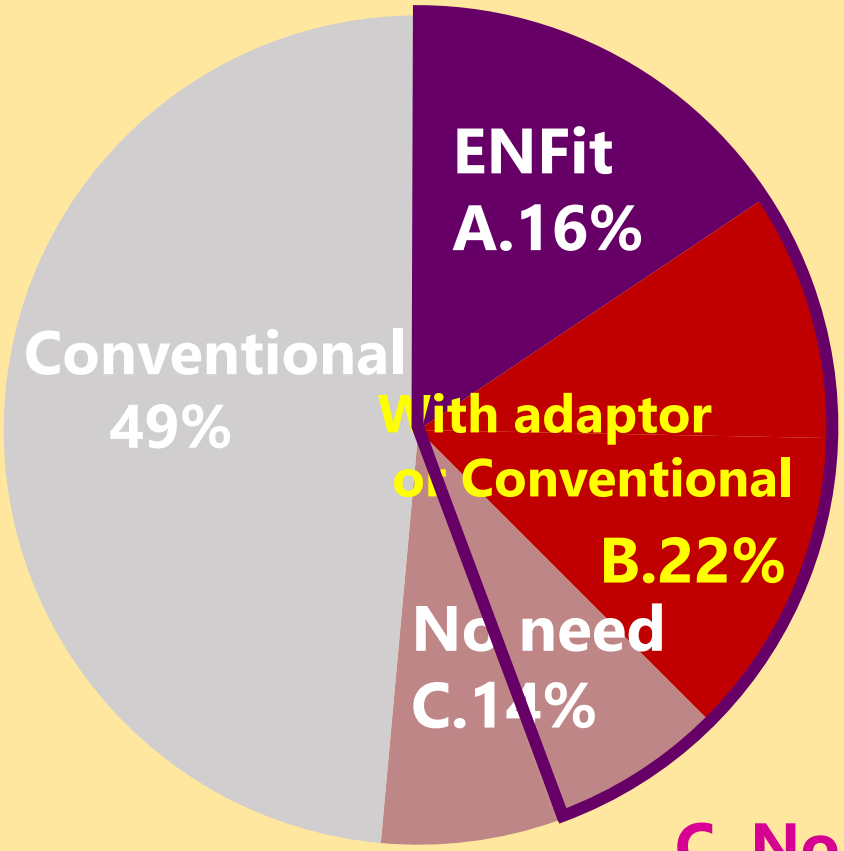
Pediatric
(206 respondents)



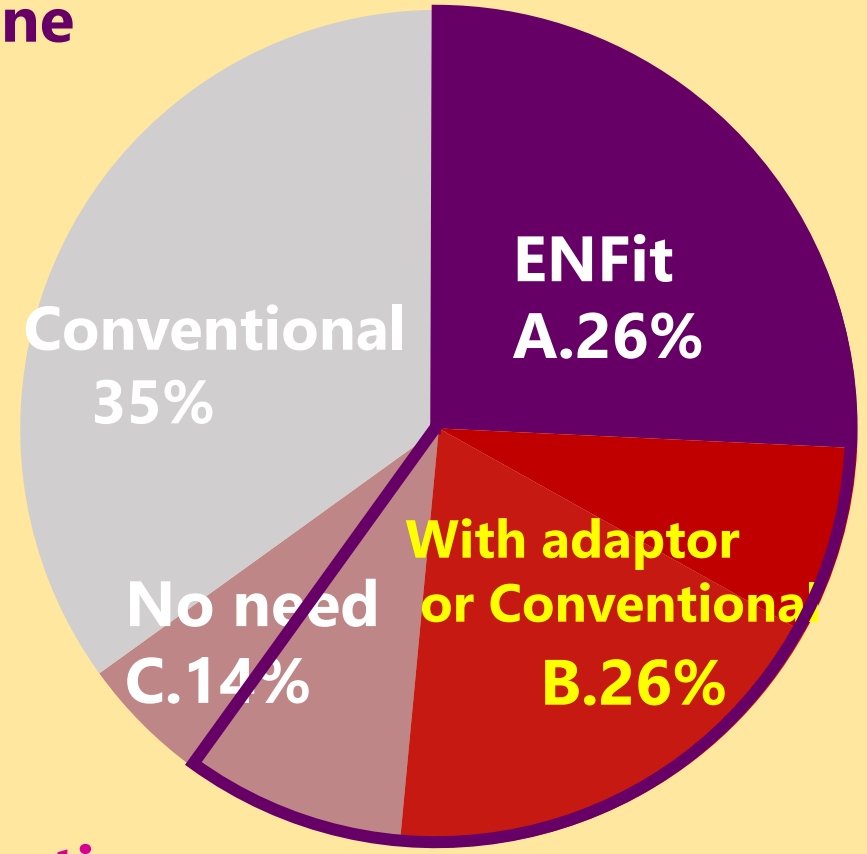
A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.

More than half of the respondents who had completely transitioned to ENFit use adaptors or conventional syringes in Gastric suction

Home care



Medical facilities



A. With ENFit alone

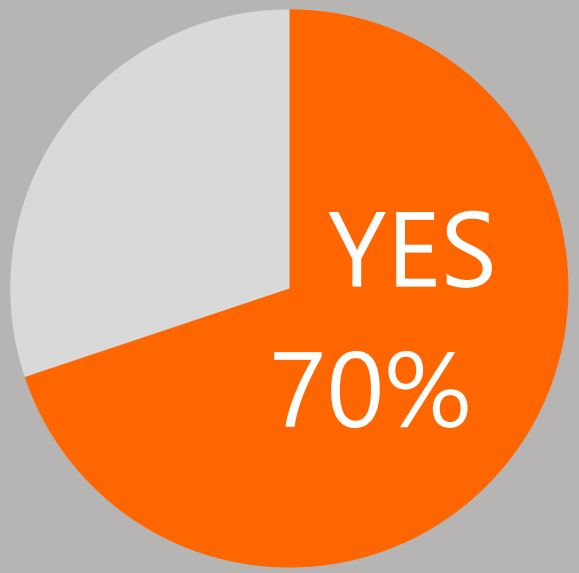
B. Other than A

C. No need for gastric suction

Some Japanese caregivers provide highly viscous blenderized natural diets through feeding tubes

The percentage of caregivers in home care using blenderized tube feeding (BTF) accounted for 70%

Participants; 667 caregivers in-home care



Do you use BTF?

Why do you use BTF?

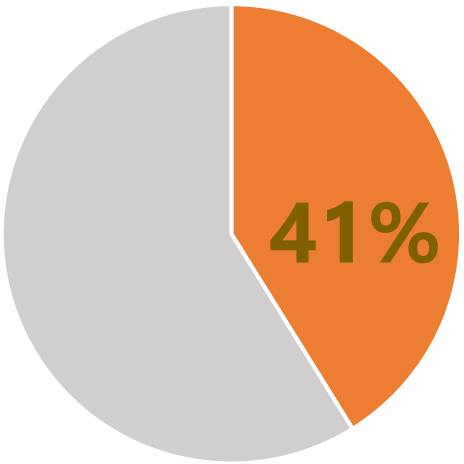
- Because of the patient's food allergies, fewer types of formulas are available
- Improved the patient's condition thanks to highly viscous BTF, including diarrhea and gastroesophageal reflux, not being able to stop it
- Natural desire to share family mealtime experiences
- Patients' requests

A questionnaire survey conducted in caregivers for children receiving home-based medical care regarding introduction of enteral feeding connector with interconnection-prevention (ISO 80369-3) Journal of Severe Motor and Intellectual Disabilities. 45(3), 2020 Kazue Asano

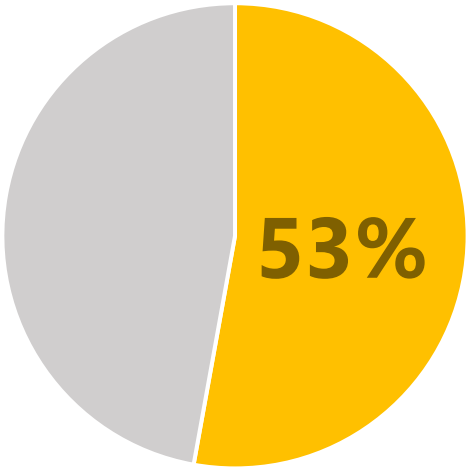
There are significant differences in the prevalence of BTF usage between pediatric and adult numbers

Home care
(907 respondents)

Adult
(243 respondents)

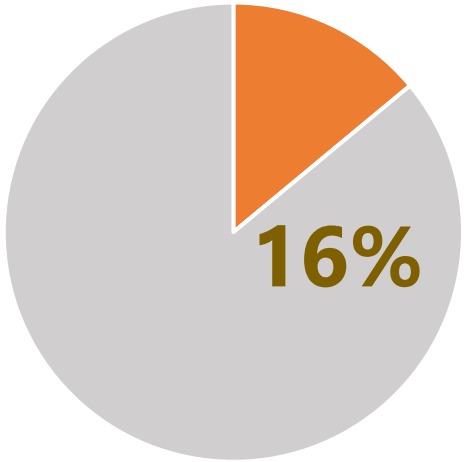


Pediatric
(702 respondents)

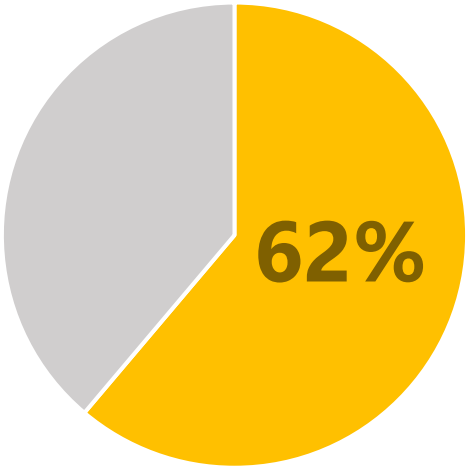


Medical facilities
(435 respondents)

Adult
(186 respondents)



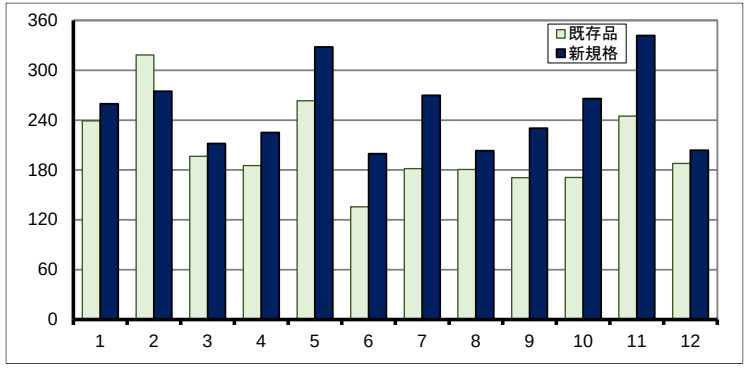
Pediatric
(206 respondents)



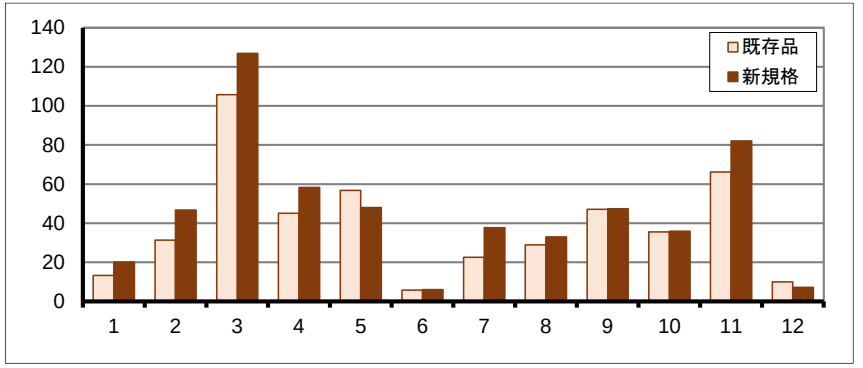
A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.

In the simulated highly viscous-BTF, the aspiration with the ENFit syringe resulted in a longer time to complete the task and greater strain on the upper extremity muscle than with the conventional syringe, which nearly doubled the manipulation force.

①time

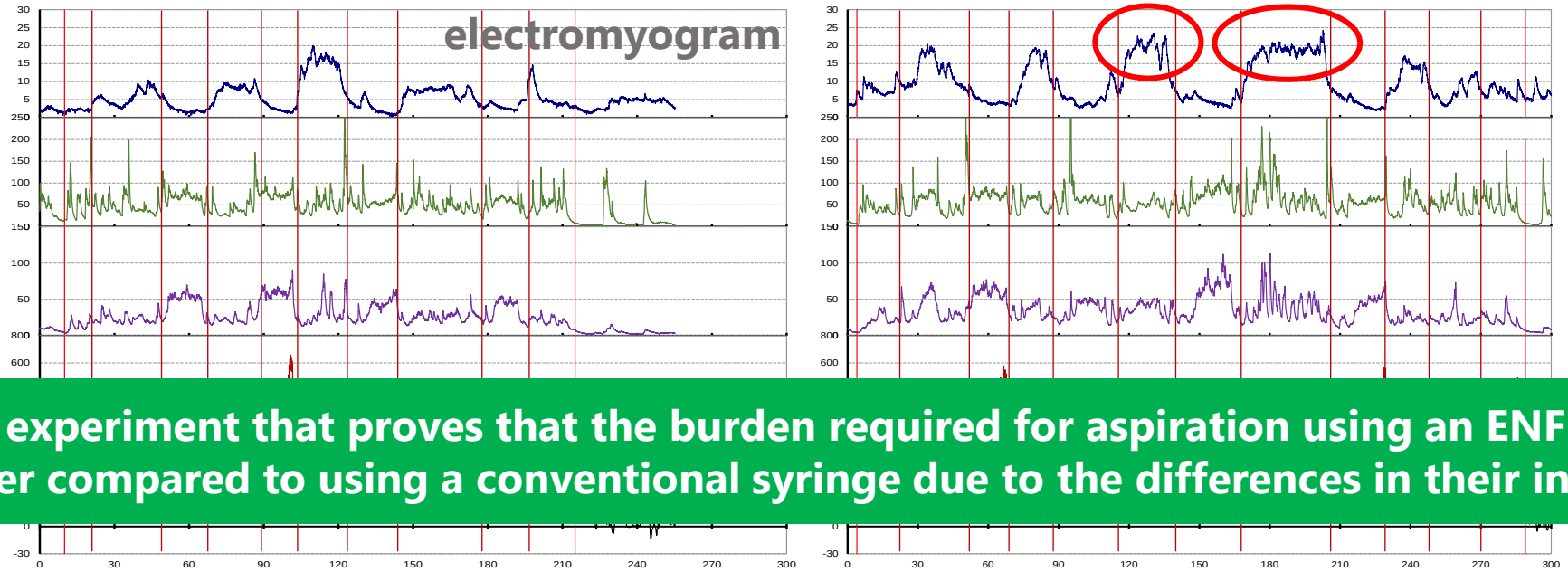


②muscle strain



Conventional syringe

ENFit syringe

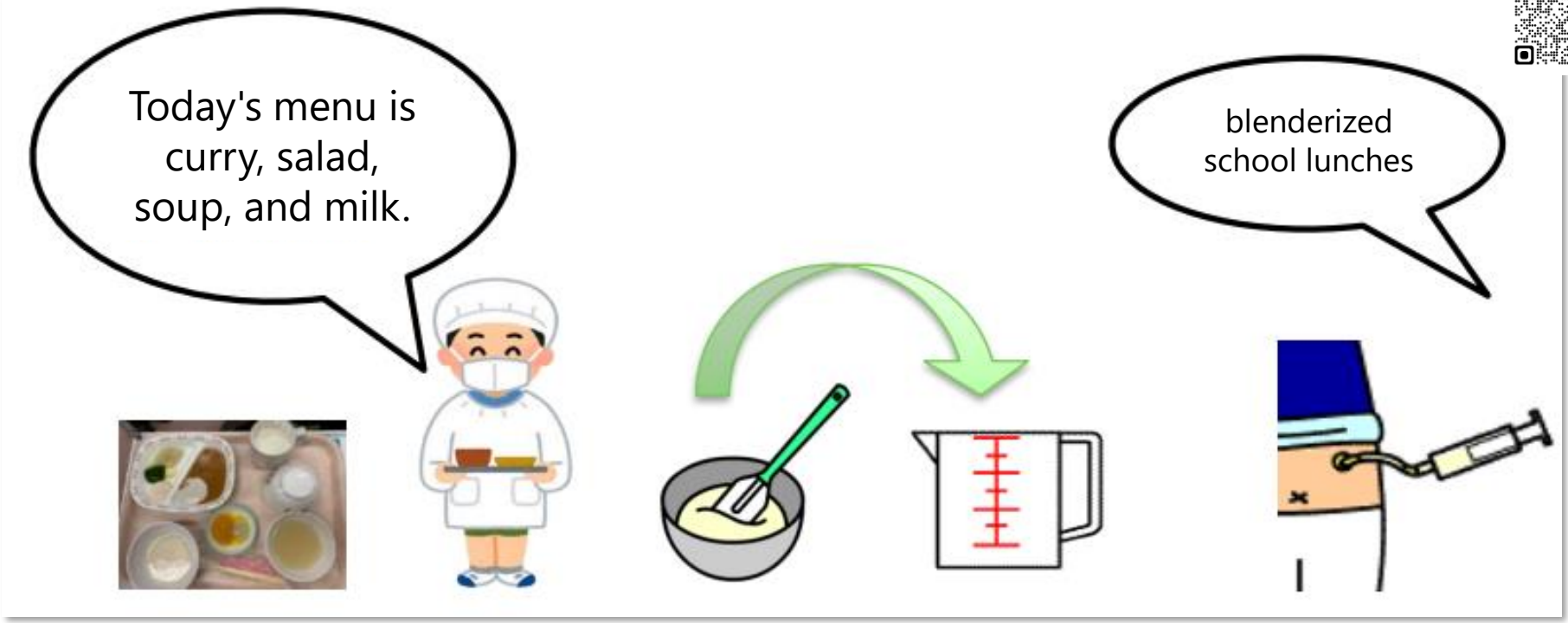


This is the first experiment that proves that the burden required for aspiration using an ENFit syringe is significantly higher compared to using a conventional syringe due to the differences in their inner diameters

Tube feeding at home and in hospitals are quite different

A mother has to take care of more than one child at a time.
It may be difficult, but she is able to feed the patient using one hand with conventional syringes

School teachers who are instructed in tube feeding provide blenderized school lunches through students' gastrostomy tubes.

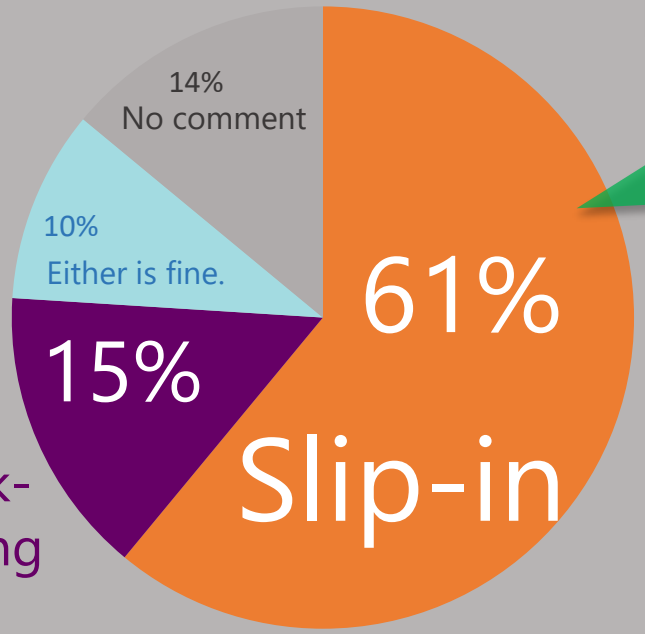


This picture was taken from the school lunch guidelines from Tokyo Metropolitan Special Needs Schools. Japan's standpoint is that school lunches are a part of education, not a break from it. By having the same meal, students learn about cooperation as well as the nutritional and cultural element of their meal.

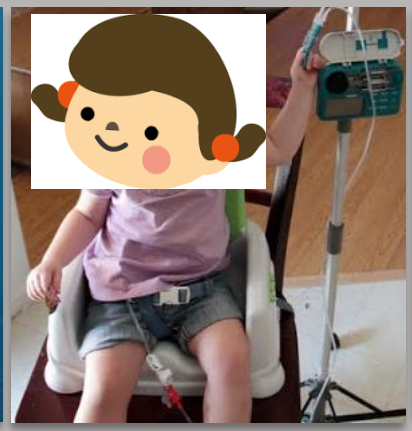
A questionnaire survey for caregivers in home care about enteral devices and potential adverse events associated with home care

Participants; 667 caregivers in-home care

Which is better? Slip-in or Lock-fitting?



For easier practices of frequent attachment and detachment (46%)
For the reduce of risk of inadvertent gastrostomy tube removal(30%)



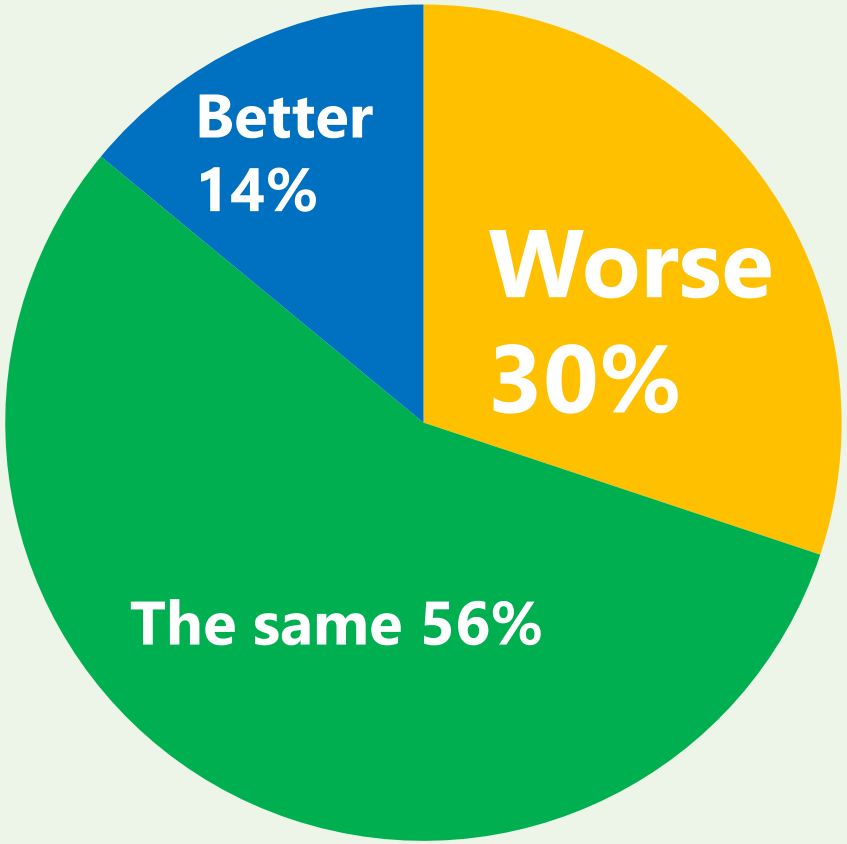
Being strangled by tubes
Foreign body ingestion

A questionnaire survey conducted in caregivers for children receiving home-based medical care regarding introduction of enteral feeding connector with interconnection-prevention (ISO 80369-3) Journal of Severe Motor and Intellectual Disabilities. 45(3), 2020 Kazue Asano

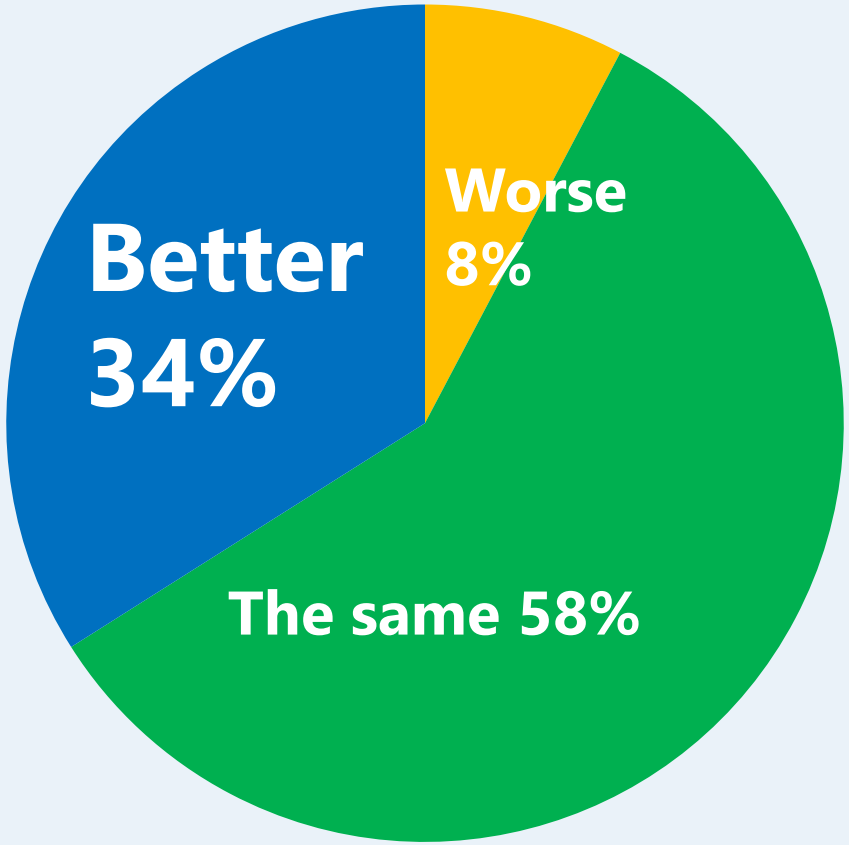
For questionnaire of overall subjective safety*, “Better” accounted for 34% in medical facilities , whereas “Worse” is 30% in Home care.

*Subjective safety refers to how safe it is to use the ENFit devices for patients.

Home care
(435;100% of all respondents)



Medical facilities
(261; 100% of all respondents)



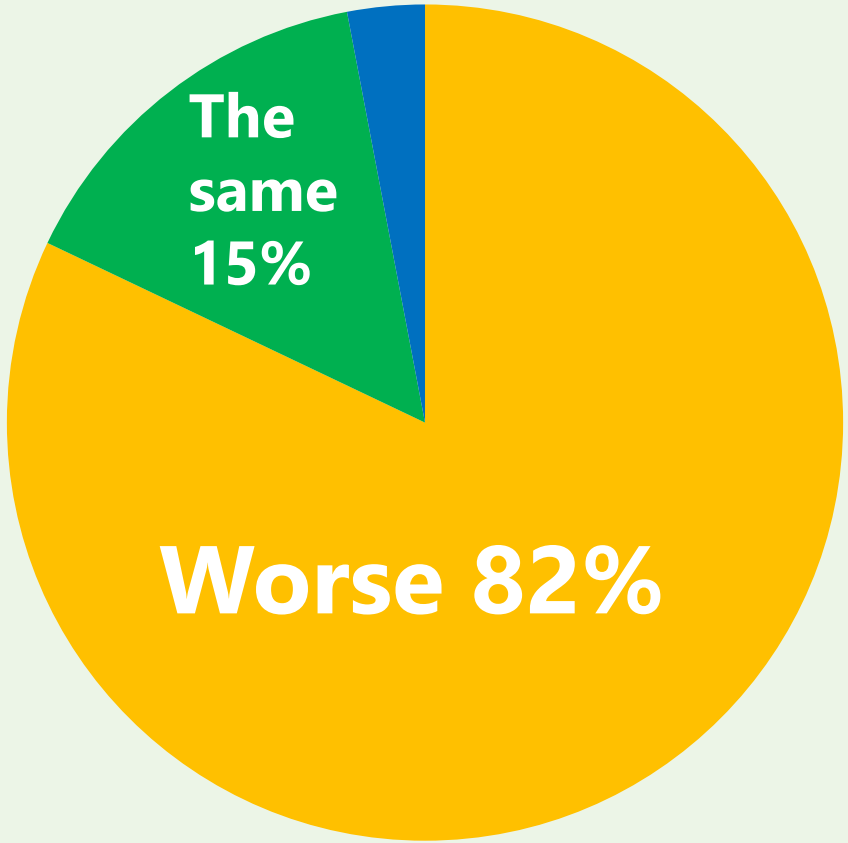
A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.

For questionnaire of overall subjective usability*, there is a big difference in the ‘Worse’ rate between Home care and medical facilities.

*Subjective usability refers to how easy it is to use the ENFit devices.

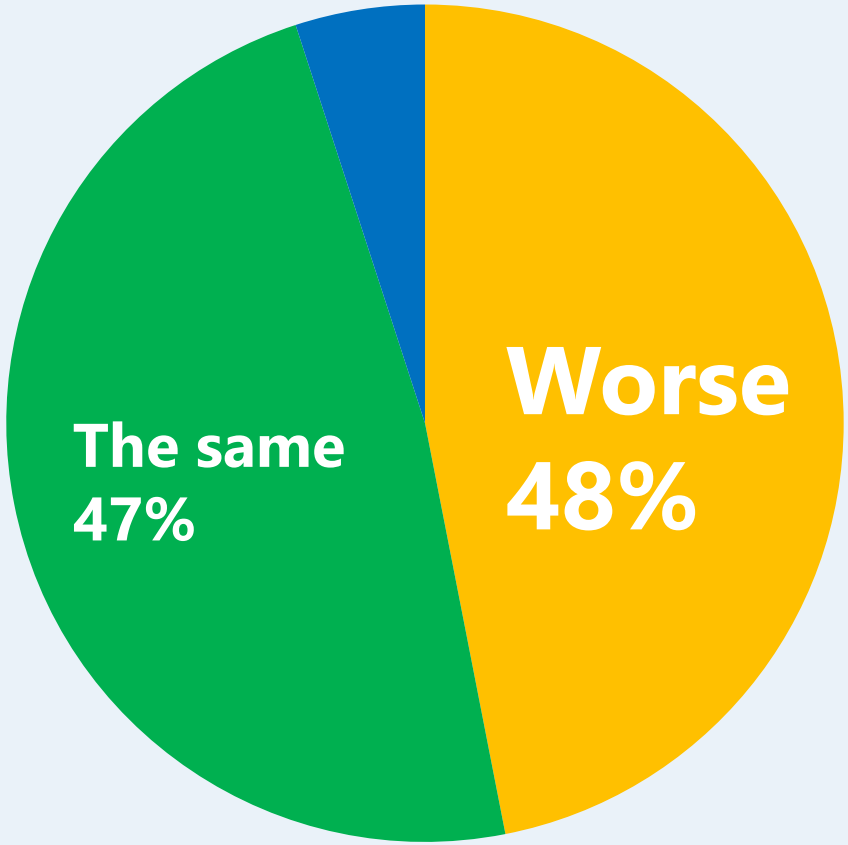
Home care

(435;100% of all respondents)



Medical facilities

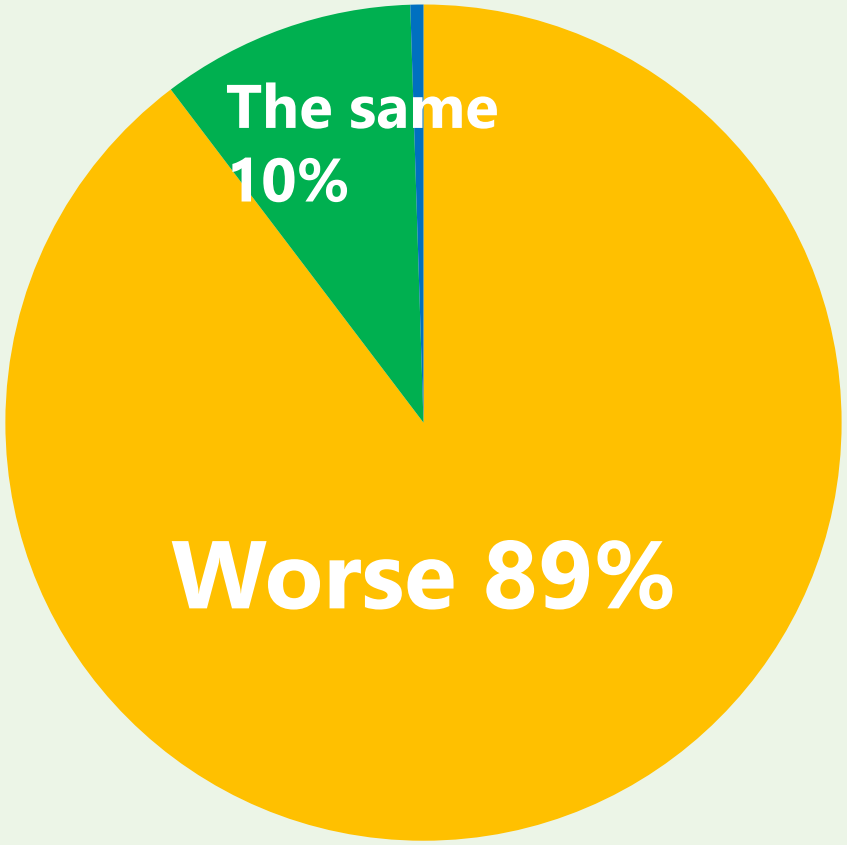
(261; 100% of all respondents)

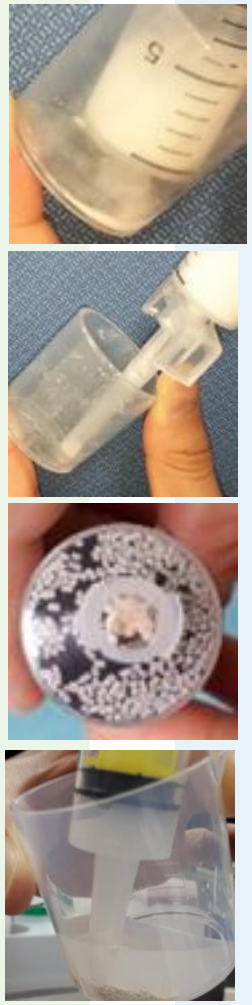


A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.

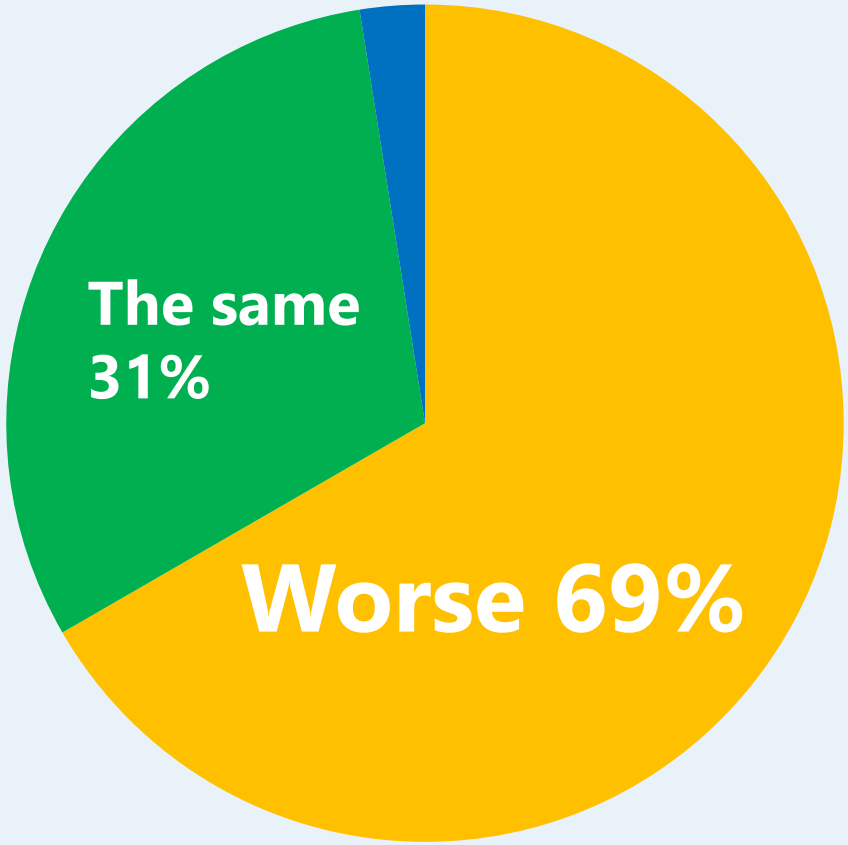
Even in medical facilities, 69% of the respondents answered “Worse” for the subjective usability of syringe filling with granular medication.

Home care
(397;91% of all respondents)





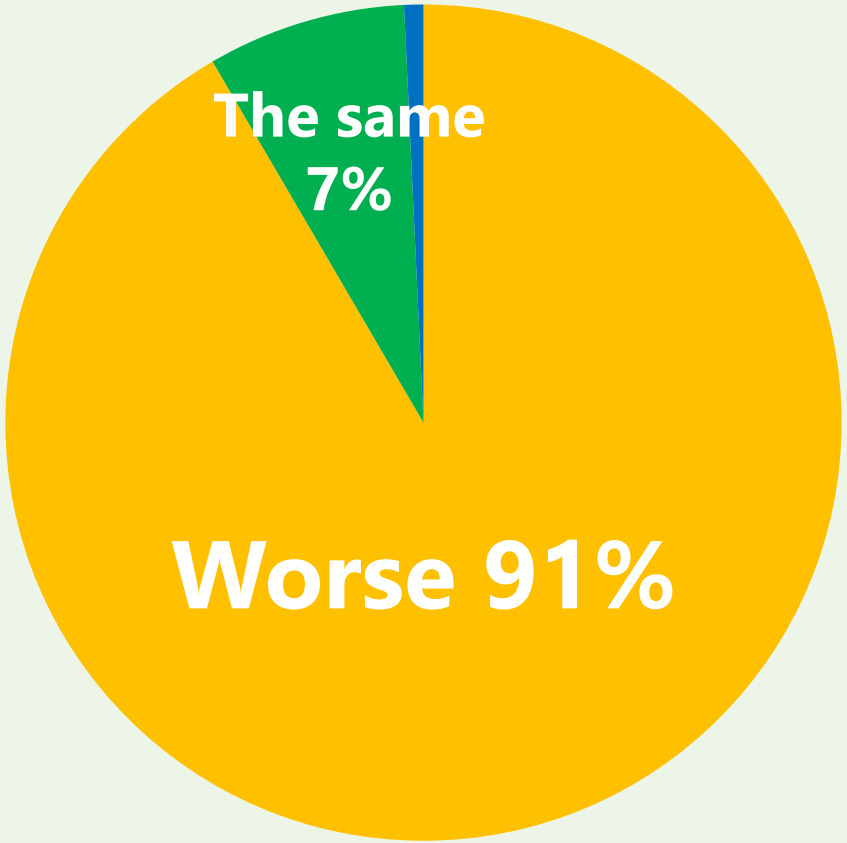
Medical facilities
(240; 92% of all respondents)

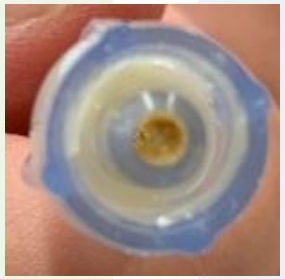


A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.

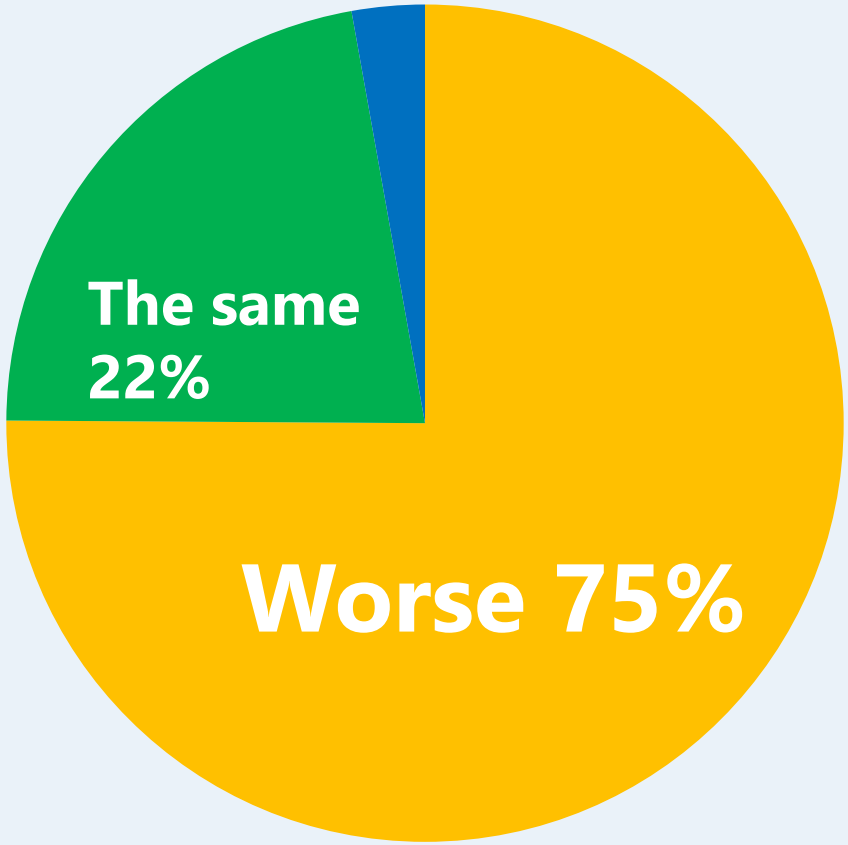
The exact same is true for cleaning where answering “Worse” accounted for 75% in medical facilities.

Home care
(404; 93% of all respondents)





Medical facilities
(249; 95% of all respondents)

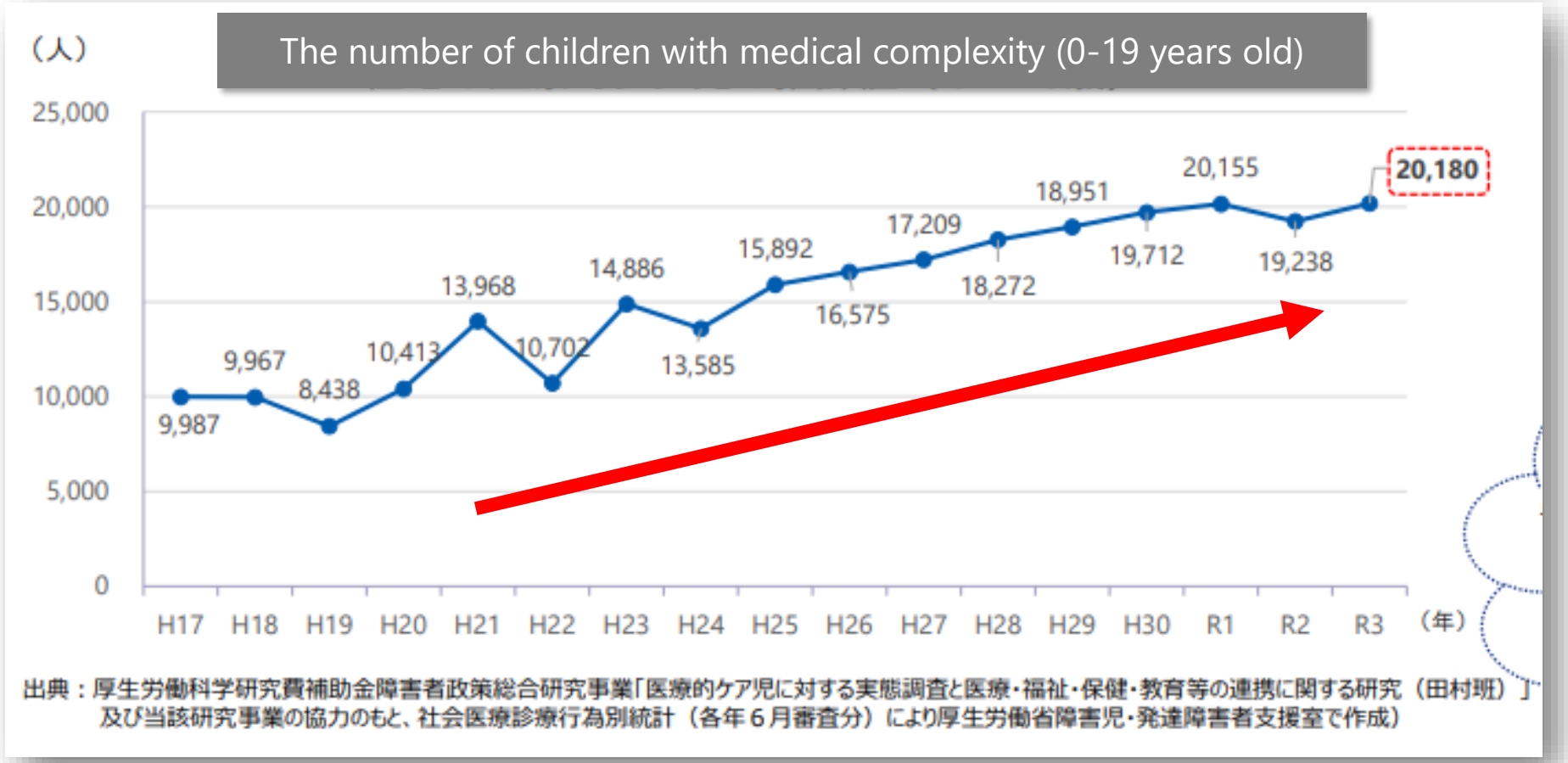


A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities conducted in September 2021 by the MHLW research subgroup.

Differences between tube feeding at home and in the hospital

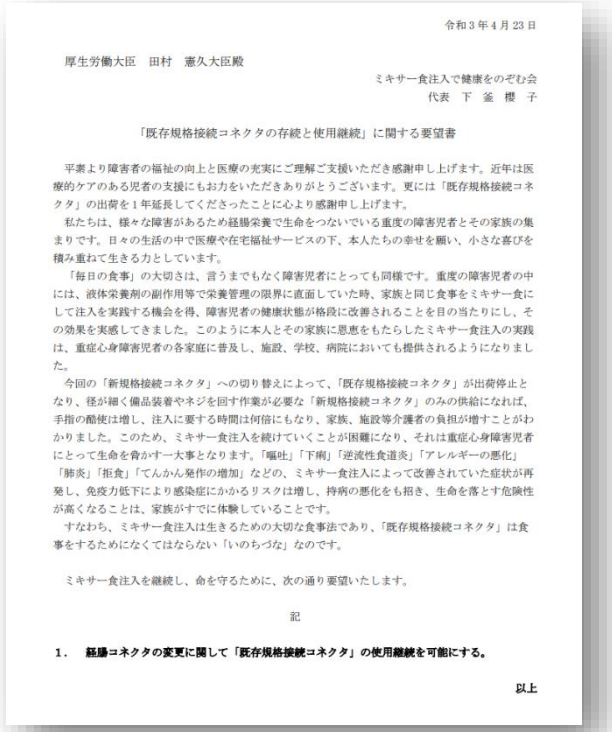
	home	Medical facilities
The purpose of tube feeding	Enjoy mealtime with family members	Caloric intake for treatment
The contents of nutrients	Highly viscous-blenderized natural diets	Liquid/Semi-solid polymeric formulas
The practitioner	Parents and Caregivers not medically trained	clinicians
Shift work	impossible	possible
Monitoring	to keep an eye on patients	through recording devices
Adaptors and syringes	Re-useable	Single-use
Electric pump	rare	common
The place to be fed	Home, schools, institutions	hospital
Adverse events associated with enteral feeding tubes	Being strangled by tubes Foreign body ingestion Inadvertent gastrostomy tube removal made them visit a hospital. Potential Infection	Potential Infection

There are currently more than 20,000 children requiring long-term medical care. 90% of them live at home and the prevalence of home care has doubled in the past 10 years.



The data from the Ministry of Health, Labor and Welfare (MHLW)

Representatives from parents and caregivers also handed over 22,000 signatures to the MHLW to request the continuation of using the existing connectors after November 2022.



令和３年４月23日

厚生労働大臣　田村　憲久大臣殿

ミキサー食注入で健康をのぞむ会
代表　下　釜　櫻　子

「既存規格接続コネクタの存続と使用継続」に関する要望書

平素より障害者の福祉の向上と医療の充実にご理解ご支援いただき感謝申し上げます。近年は医療的ケアのある児者の支援にもお力をいただきありがとうございます。更には「既存規格接続コネクタ」の出荷を１年延長してくださったことに心より感謝申し上げます。

私たちは、様々な障害があるため経腸栄養で生命をつないでいる重度の障害児者とその家族の集まりです。日々の生活の中で医療や在宅福祉サービスの下、本人たちの幸せを願い、小さな喜びを積み重ねて生きる力としています。

「毎日の食事」の大切さは、言うまでもなく障害児者にとっても同様です。重度の障害児者の中には、液体栄養剤の副作用等で栄養管理の限界に直面していた時、家族と同じ食事をミキサー食にして注入を実践する機会を得、障害児者の健康状態が格段に改善されることを目の当たりにし、その効果を実感してきました。このように本人とその家族に恩恵をもたらしたミキサー食注入の実践は、重症心身障害児者の各家庭に普及し、施設、学校、病院においても提供されるようになりました。

今回の「新規格接続コネクタ」への切り替えによって、「既存規格接続コネクタ」が出荷停止となり、径が細く備品装着やネジを回す作業が必要な「新規格接続コネクタ」のみの供給になれば、手指の酷使は増し、注入に要する時間は何倍にもなり、家族、施設等介護者の負担が増すことがわかりました。このため、ミキサー食注入を続けていくことが困難になり、それは重症心身障害児者にとって生命を脅かす一大事となります。「嘔吐」「下痢」「逆流性食道炎」「アレルギーの悪化」「肺炎」「拒食」「てんかん発作の増加」などの、ミキサー食注入によって改善されていた症状が再発し、免疫力低下により感染症にかかるリスクは増し、持病の悪化をも招き、生命を落とす危険性が高くなることは、家族がすでに体験していることです。

すなわち、ミキサー食注入は生きるための大切な食事法であり、「既存規格接続コネクタ」は食事をするためになくてはならない「いのちづな」なのです。

ミキサー食注入を継続し、命を守るために、次の通り要望いたします。

記

１．　**経腸コネクタの変更に関して「既存規格接続コネクタ」の使用継続を可能にする。**

以上

The MHLW decided to prolong the deadline and required to be more specific about potential difficulties with the implementation of ENFit syringes to a research group

A cross-sectional survey with 2 types of questionnaires conducted during the transition period in Japan

Purpose	To understand the overall trends of issues associated with ENFit devices
Date	September 13,2021 to October 15, 2021
Form	Website questionnaire using Google form
Participants	1) Patient's caregivers to reflect home care 2) Chief managers from each ward providing enteral feeding at medical facilities
Questionnaires	
Basic-	For all participants The patients' age, the type of feeding tube, the contents of EN, how to deliver nutrients, the practice of medication administration, the devices for gastric suction
Advanced-	For limited respondents who had completely transitioned to ENFit Their experiences with ENFit devices compared to conventional ones
Statistics	Conventional/Transition and Pediatric/Non-pediatric rate differences were analyzed by a chi-square test
Ethical Committee	The Biwakogakuen Kusatsu Medical and Welfare Center for Disabilities Ethics Approval number; 2021103

The MHLW research group title;

Research to understand and formulate measures to address the issues associated with the transition to the new small-bore connector products in the EN field

Principal Researcher;
NAGAO Yoshimasa

Nagoya University Hospital
Department of Patient Safety
Professor

The duration;
May 2021-March 2022

Conclusion;

We have developed a policy recommendation regarding the transition of the small-bore connector products in the EN field. We understand the necessity of promoting the transition to standardized products to prevent accidental misconnections and to ensure a stable supply.
However, it should also be considered that blenderized diets and semi-solid nutrients have been widespread in the EN field in Japan, contributing to the quality of life of EN patients.
In the long run, developing innovative EN products that meet the new standard and can be used safely and conveniently is desirable. Besides, in the meantime, if it is difficult or unsafe to use the new standard product, the old standard product is allowed to be used under certain conditions, such as having appropriate medical reasons for using the old standard product, obtaining informed consent for the risks of its use, and informing surrounding supporters of its use.

The MHLW research subgroup conducted 6 studies regarding small-bore connector products

本邦における重症心身障害児・者の医療的ケア領域での当該製品の切替え伴う課題に係る調査

（分担研究者：びわこ学園医療福祉センター草津　施設長　口分田政夫）

研究要旨　小口径コネクタ製品の切替えに伴う重症心身障害（以下、SMID）領域での課題を抽出した。まず、全体的傾向の把握のために、(1)経腸栄養に関わる医療従事者、介護者の多数を対象とした大規模アンケート調査を行った。次に、SMID 領域に特有の課題を具体化し、対応策を提示した。SMID 領域では、小口径コネクタ製品をミキサー食の注入、薬剤投与、消化管からの排気排液など医療や医療的ケアの様々な場面で使用し、さらに実施者や実施場所は医療従事者や病院に限定されることなく、ケアは日常的に継続される。このような状況で想定される介護者の負担を客観的に示すために、(2) 筋電図を用いたミキサー食注入時における筋負荷の測定を行った。SMID 領域での薬剤投与に関しては、体重に合わせた徐放性剤や顆粒剤、あるいは、漢方が処方される場合があり、簡易懸濁についても必ずしも実施されているわけではない。薬剤を正確に投与することは病態のコントロールに必要不可欠であり、さらに、薬剤によるチューブの閉塞は、緊急受診が必要となるため本人家族にとって負担が大きい。したがって、(3)小口径コネクタ製品を用いた薬剤投与の正確性についての模擬検証を実施し、また、(4)切替えで起こり得るチューブ閉塞の危険性とデバイス単回使用時のコストについてのシミュレーションを併せて行った。排気排液に関しては、(5)SMID 症例の術後や急性期治療を担う外科、小児外科医へのアンケート調査を行い、具体的なコメントを聴取した。最後に、SMID 児・者の領域では在宅を中心にミキサー食注入が広がりつつあり、その注入の困難さが今回の切替え問題の発端となった。(6) ミキサー食注入者の腸内細菌叢の解析と大腸の有機酸測定を行い、ミキサー食注入の効果を客観的に提示した。

The MHLW research subgroup title;

Research on issues associated with the transition to small-bore connector products in the field of EN for children and adults with severe motor and intellectual disabilities in Japan

The MHLW research subgroup member;

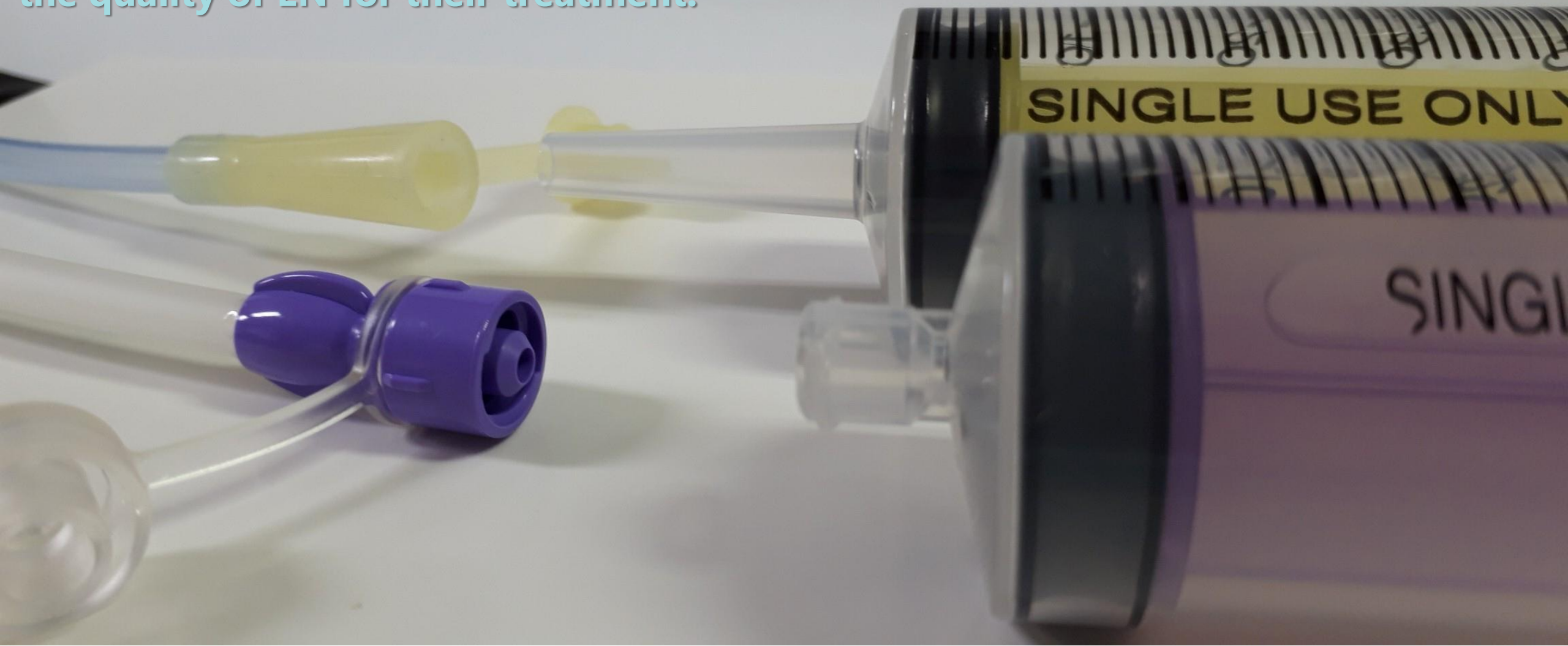
KUMODE Masao, pediatrician
ASANO Kazue, Pediatrician
NAGURA Michiaki, Pediatrician
NAGAE Akiko, Pediatrician




Research in detail;

(1) A cross-sectional survey with 2 types of questionnaires for HEN and medical facilities.
(2) Upper extremity strain felt by caregivers during injecting viscous liquid diet to children requiring tube enteral feeding: a simulated experiment focusing on the differences between connector shapes of injection syringes
(3) An in-vitro study comparing several methods of medication administration via a conventional connector and ENFit
(4) To make a list of insoluble granule medications that tend to be clogged through the smaller diameter of the connectors
(5) Questionnaire survey of pediatric surgeons regarding devices for gastric venting or suctioning
(6) Analysis of intestinal microflora and measurement of Short-Chain Fatty Acids in 30 participants with EN

Some patients need one tube for both functions: suction and infusion, others need highly viscous BTF to maintain their healthy condition. Japan decided to use conventional devices for those patients to maintain the quality of EN for their treatment.



CONCLUSION

Since EN is the most basic medical care that can be provided even by non-medical personnel, devices need to be more universal. Most widely-used standards of enteral devices may need not only to reduce misconnections but also take into account the people who use them, the situations in which they will be used, and the ideal content substances to be delivered to the body through them.
ISO80369-3 is the only standard of five other applications by which even non-medical personnel should deliver substances other than liquid or gases, aspirate and deliver something highly viscous or granular, and drain or vent through tubes just before feeding.

Let me share with you a video of a boy being fed by BTF.
I support him and he is the light of the world.

For all patients in the world.
It was my pleasure to be here and thank you for listening.