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Evolution and future prospects of Japan's law for supporting children requiring medical care

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Abstract

The "Law Concerning Support for Children with Medical Care and Their Families" was enacted by the Japanese Diet on June 11, 2021. The challenges surrounding children requiring phlegm suctioning and tube feeding first gained attention in the context of school education in 1988. Since then, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW) have implemented various measures to address these issues. These efforts include clarifying the legal interpretation of non-medical personnel performing such acts, authorizing specific procedures under the revised Social Worker and Care Worker Law, and distinguishing acts that are not fundamentally considered medical. This study examines the historical development of these measures, identifies challenges regarding community integration for children with medical care needs, and discusses potential future directions.

keywords: Law concerning support for children with medical care and their families, medical care legislation, medical practice, injunction against substantive illegality, authorized specific acts, non-medical acts

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I. Introduction

Advances in perinatal and emergency medicine have significantly improved the survival rates of newborns and other infants. Concurrently, the Ministry of Health, Labour and Welfare (MHLW) in Japan has actively promoted the transition from hospital-based care to home-based care as part of its administrative policy. This shift has facilitated the integration of individuals with breathing disorders, eating and swallowing dysfunctions, and voiding issues into home and community settings, often necessitating ongoing medical interventions such as sputum suctioning, oxygen therapy, ventilators, tube feeding, and urinary catheterization. As of 2021, the MHLW estimated the number of such children (aged 0-19) requiring these forms of care to be approximately 20,000 –a figure that has doubled over the past decade [1].

To address these challenges, the "Act on Support for Children with Medical Care and Their Families" (hereinafter referred to as the "Law for Supporting Children with Medical Care") was enacted by the Japanese Diet on June 11, 2021, promulgated on June 18, and implemented on September 18 of the same year. In 1988, the Tokyo Metropolitan Board of Education expressed the opinion that children requiring phlegm suctioning and tube feeding should receive schooling primarily through home visits [2]. The creation of the term "medical care" itself dates back to 1991 in a report by the Osaka Prefectural Board of Education [3]. During the late 1980s, the issue of medical care for children in specialized schools became a point of contention, particularly in metropolitan areas. Education and medical professionals debated whether activities such as phlegm suctioning and tube feeding constituted "medical practice" or "activities of daily living" and deliberated on who should be responsible for providing such care. Efforts to ensure equitable education for children requiring medical support

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led to an expansion of teaching resources and partnerships with home nursing stations across the country.

In 2004, an official interpretation of the law allowed non-medical personnel, such as helpers and teachers, to perform specific medical procedures, such as phlegm suctioning provided that certain conditions are met to prevent "substantive illegality" [4]. Subsequently, the 2005 issuance of the Interpretation of Article 17 of the Medical Practitioners Act, Article 17 of the Dentists Act, and Article 31 of the Public Health Nurses, Midwives, and Nurses Act delineated actions not classified as medical practice in principle [5]. This was followed by the 2012 revision of the Social Worker and Care Worker Act, which codified the roles of care workers, helpers, teachers, and child care workers in providing medical care [6]. While expanding of roles of such care-givers, the reliance on nurses for advanced medical care, such as ventilator management intensified, after 2016, when the term "advanced medical care" gained prominence [7].

This study reviews the evolution of medical care for children requiring support, spanning from the initial recognition of the issue in 1988 to the enactment of the Law for Supporting Children with Medical Care in 2021. In addition, it explores the challenges and potential future directions for enhancing community life for these children and their families.

II. History of the law for supporting children with medical care

Table 1 summarizes societal trends regarding Medical Care in Japan.

1. Period 1 (-1997): The Dawn of Medical Care

Advances in medical technology during this period resulted in improved survival rates for children, leading to an increase in those discharged from hospitals to home care. In Osaka Prefecture and Yokohama City, schools for disabled children integrated aspects of home care into school life. Teachers, guided by guardians, performed caregiving tasks as part of daily living. Notably, since 1972, Yokohama City had implemented medical safety initiatives in schools, including visits from pediatric neurologists and rehabilitation physicians, while Osaka Prefecture assigned pediatric neurologists as school physicians [8,9].

In 1988, the Tokyo Metropolitan Board of Education classified phlegm suctioning and tube feeding as medical procedures, establishing guidelines for school attendance that required either home-based education or accompaniment by a parent or guardian. During this time, various terms, including "medical practice," "medical-like practice," and "daily life practice," were utilized to describe these activities.

The term "Medical Care" first appeared in a 1991 report by the Osaka Prefectural Board of Education's Investigative Committee on the Way of Cooperation with Medical Care. Matsumoto emphasized that "care" referred to nursing rather than curative treatment and highlighted its educational context within schools [10]. The words "medical care" and "subjects" were included, because such care is carried out as part of an educational act in an educational setting.

Consequently, there were discussions among educators and medical personnel as to whether suctioning of sputum and tube feeding are considered "medical practices" or "activities of daily living," as well as who should be in charge of such activities.

In 1992, the Tokyo Metropolitan Board of Education launched a medical system development project to study procedures and training systems for teachers to provide medical care when parents cannot accompany their children, as well as the assignment of medical advisors, such as pediatric neurologists [11]. This method of providing medical care by teachers who are requested or commissioned by the guardians and who have received prior training from a medical professional is a "response based on the inhibition of illegality" (see below), resulting in initiation of a model project by the then Ministry of Education in 1998.

Conversely, based on the home-visit nursing system that began in 1992, some local governments have addressed this issue by dispatching nurses from home-visit nursing stations [12]. In 1997, Miyagi Prefecture began dispatching nurses from home nursing stations to schools, with the local government bearing the cost of dispatching the nurses (health insurance cannot be utilized because it is limited to in-home care), in what was refferd to as the "Miyagi Method" [13]. Subsequently, in 2000, Shiga Prefecture introduced the "Shiga Prefecture Home Visiting Nurse Subsidy Program for Severely Disabled Children" [14].

Although the utilization of home-visit nursing stations was a pioneering approach in utilizing the existing system, there were schools in which teachers were not even allowed to pass contact sheets between parents and home-visit nurses within the school, therefore clearly separating education and medical care. Furthermore, financial and operational issues, such as the absence of remuneration during school vacations, led to a gradual shift toward employing nurses directly as part-time staff by boards of education.

It is necessary to understand that the background to the introduction of medical care by teachers in this first period was a situation in which medical care could not be provided

Table 1. Societal trends regarding Medical Care in Japan

Field / Educational Perspective	Society	Medical Care	Welfare	Education
Period 1 (-1997) **Dawn of medical care: The emergence of issues and the birth of "Medical Care"**	Increase in Older Births → Decrease in neonatal mortality rate ← Development of equipment for home medical care Policy to control social security costs (Aging Society)	Increase in low birth weight babies Advances in Medical Technology 1981: Ministry of Health and Welfare referral of patient/family insulin injections 1992: Home health care nursing (elderly) 1994: Home health care nursing (disability)		1979: Mandatory schooling for children with disabilities 1988: School attendance issues become apparent in Tokyo 1991: The term "Medical Care" coined in Osaka Prefecture
Period 2 (1998-2004) **A period of confusion in medicine, welfare, and education**	2000: Long-term care insurance system 2003: Assistance Expenses System	1999: Nursing Association opposition ← 2002: Pediatric neurology society request	1999: General Affairs Agency Administrative Recommendations ← 2003: Report on ALS Patients	1998: Practical research by the Ministry of Education 2002: Visiting Nursing Scheme 2004: Report on schools for the disabled
Period 3 (2005-2011) **The Era of response based on the rejection of illegality**	2005: Nursery school enrollment lawsuit 2006: Services and support for Persons with Disabilities Act 2008: Death of pregnant women → 2008: Vision for long-term care	Emergence of neonatal intensive care unit (NICU) shortage	2005: Report on non-ALS patients 2005: Ministry of Health, Labour and Welfare Notification (in principle, non-medical) 2010: Report on Special Care	2007: First year of special support education 2011: Notification of medical care at special-needs schools, etc.
Period 4 (2012-2015) **The Era of Legal Responses**	2012: Partial revision of the Social Worker and Care Worker Act (Certified Specified Action Worker)			
	2013: Law for Elimination of Discrimination against Persons with Disabilities (prohibition of discriminatory treatment and provision of reasonable accommodation), Comprehensive support for Persons with Disabilities Act			
	2014: Ratification of the Convention on the Rights of Persons with Disabilities			
Period 5 (2016-2020) **The Era of spillover effects from ratification of the Convention on the Rights of Persons with Disabilities**	2016: Partial revision of the Child Welfare Law (local governments obliged to make efforts)			
	2017: Training for coordinators of Children with Medical Care, etc.			
	2018: Partial amendment of the Comprehensive support for Persons with Disabilities Act	2018: Emergency tracheal cannula reinsertion	2017: Model Project to Support Childcare for Children with Medical Care	2018: Interim summary of the study group 2019: Notice of future responses
	2019: Comprehensive support project for children with medical care, etc.			
Period 6 (2021-Present) **Passage of the Law for supporting Children with Medical Care**	2021: Act for supporting Children with Medical Care (Responsibilities of the National and Local Governments)			
			2021: Promotion of support for Children with Medical Care in daycare centers, etc. (administrative communication)	2021: Medical Care Implementation Support Materials, Medical Care Nursing Staff (Revision of School Education Law Enforcement Regulations)

even if nurses were assigned to places other than medical institutions, such as, for instance, schools that do not have physicians. In 1992, "home care" was included in Article 1-2, Paragraph 2 of the Medical Care Act, while home-based nursing care for the elderly was instituted in 1992, and home-based nursing care for the severely disabled was institutionalized in 1994. This enabled nurses to provide medical services outside of medical institutions under the direction of a physician. However, around 1998, when the Ministry of Education's model project commenced, the purpose of the program was not fully understood, and there were some reports of schools being affected by comments from attending physicians who stated that they could not issue a letter of instruction to a nurse they did not know.

In the case of the Tokyo Metropolitan Government, nurses were first assigned to schools when the Tokyo Municipal Komyo School, the first public school for physically handicapped children in Japan, was opened (June 1, 1932) [15] (enforced on April 1, 1995) [16]. At the national level, the Ministerial Ordinance Partially Revising the Enforcement Regulations of the School Education Law (promulgated on August 23, 2021, and enforced on the same day) stipulated in Article 65-2 that the new "Medical Care Nursing Staff shall provide constant medical care (meaning respiratory management using a ventilator, sputum suctioning, and other medical treatment; the same applies, hereinafter) for children in whom such care is indispensable them to lead their daily and social life at elementary schools" and the name and job description of nurses working in schools were stipulated.

The first phase was a time when the issues of medical care became apparent, and each municipality explored various strategies to address them. This led to the second phase, the model project of the Ministry of Education, Culture, Sports, Science and Technology (MEXT) in 1998, which initiated a more structured approach to supporting children requiring medical care.

2. Second Period (1998-2004): A time of confusion in medical care, welfare, and education

In 1998, the then Ministry of Education launched the "Practical Research on Cooperation with Welfare and Medical Care in Special Education," in which teachers were to provide part of the medical care under the backup of nurses. The initial policy was to reach a conclusion and generalize the project within two years. However, in September 1999, the Japan Nurses Association strongly opposed the administrative recommendation [17] made by the then Agency of

Internal Affairs and Communications to the then MHW, a recommendation which had aimed to allow home caregivers to perform a range of physical care-related activities. This led to a shift in emphasis in the Ministry of Education's research toward the creation of a system centered on nurses.

In response to this national movement, a movement of parents' organizations was also born. The National Federation of PTAs of Schools for the Handicapped and Physically Disabled prepared the memorandum "When should parents with children requiring medical care wait?" , and also stated that "it will be important in the future to have a place to exchange and share information on how each municipality's own efforts and the national guidelines will evolve, and how to improve the quality of life of children in need of medical care, such as education and community care, as well as to exchange opinions, practices, and responses to issues [18]." In response, the National Network for Medical Care, comprising 34 organizations, was established on November 23, 2002 [19].

In March 2002, a joint council of the MEXT and the MHLW proposed a "Home-Visit Nursing Scheme" [20] for utilizing home-visit nursing stations; however, it was not included in the FY2003 budget. In August 2003, MEXT issued a notification encouraging local governments to assign personnel with nursing qualifications flexibly, either as full-time teachers and staff or as part-time staff, by utilizing available teaching quotas [21]. Consequently, several local governments, including Chiba, Niigata, Toyama, Yamanashi, Shizuoka, Aichi, Wakayama, Okayama, Kumamoto, and Okinawa, which had been allocating nurses utilizing the government's Special Grant for Emergency Regional Employment Creation starting in 2001, switched to utilization of part-time nurses by utilizing the fixed number of faculty members, or as projects unique to each local government when the program was terminated in 2004.

Furthermore, on January 15, 2003, Nagano Prefecture applied to the government's Special Zones for Structural Reform to "allow relatively simple medical procedures to be performed by licensed nursing teachers in schools for the handicapped" [22]. In response, the MEXT responded, "We will clarify that nursing teachers with a nursing license in schools for the disabled can perform relatively simple medical procedures under the direction of a doctor, as part of the school duties of the school for the disabled." This response had a strong impact on those involved with school nurse-teachers. In February of the same year, four school nurse teacher organizations submitted a request to the MEXT not to distinguish between nurse teachers with and without nursing licenses, arguing that the existing curricula had already addressed the necessary competencies [23].

The second phase was a period of confusion, not only with regard to school issues, but also in terms of medical, welfare, and educational issues. On June 9, 2003, the "Subcommittee on Home Care Support for ALS Patients by Nurses, etc." established by the MHLW compiled a report and proposed a law that would allow non-medical personnel to conduct suctioning of sputum and other medical procedures under certain conditions. On September 17, 2004, a report entitled "Summary of Medical and Legal Arrangements for Suctioning of Sputum in Schools for the Blind, Deaf, and Physically Handicapped" was issued, which indicated the direction that medical care in schools for the blind, deaf, and children with disabilities would take.

3. Third Period (2005-2011): The era of response based on inhibition of Illegality

During this period, the MHLW conducted a series of studies to explore the permissibility of non-medical personnel performing medical procedures such as sputum suctioning. Reports were compiled on various items, including care for ALS patients [24], medical care in schools for the blind, deaf, and disabled [25], responses beyond ALS patients at home [26], and care in special nursing homes [27]. In 2005, the MHLW issued a notice entitled "Interpretation of Article 17 of the Medical Practitioners Act, Article 17 of the Dentists Act, and Article 31 of the Public Health Nurses, Midwives, and Nurses Act," clarifying actions that were not considered medical acts.

On November 12, 2008, at the 6th meeting of the MHLW's Bureau of Gerontology's "Vision for Caregiving with Peace of Mind and Hope," a preliminary proposal was presented, proposing the establishment of a "medical caregiver (tentative name)" that would enable caregivers to perform medical procedures necessary to support daily life, such as tube feeding and sputum suctioning [28], However, the proposal was quickly withdrawn due to objections regarding the creation of a new job title. However, this idea was later reflected in the training program for caregivers.

In this manner, while the handling of sputum suction by non-medical personnel was under discussion, the handling of sputum suction by medical personnel other than physicians and nurses was also being discussed. In response to a Diet member's question on November 22, 2004, the Government of Japan stated that, "Physical therapists do not generally acquire the knowledge and skills necessary to perform sputum suction in their training courses, and at this point, we believe that careful consideration is necessary regarding allowing physical therapists to perform sputum suction as their duties, including when performing such services on amyotrophic lateral sclerosis patients." The Cabinet decided to allow physiotherapists to perform this task (November 30, 2004, Cabinet Office, Lower

House, Quality Assurance, No. 161-49). Subsequently, on April 30, 2010, the Director-General of the Medical Affairs Bureau of the MHLW issued a notice, "On the promotion of team medicine through collaboration and coordination among medical staff" [29], because the nature of medical care was being fundamentally questioned, as the increasing sophistication and complexity of medical care was causing exhaustion in medical workplaces. The notice included the suctioning of sputum for rehabilitation-related occupations (physical therapists, occupational therapists, and speech-language pathologists) and clinical engineers as part of "physical therapy," "occupational therapy," and "speech and language training and other training" under the "Physical Therapy Act," and"operation of life support equipment" under the "Clinical Engineering Technician Act."

Around this time, due to a lawsuit (decided in 2006) [30,31], the issues of emergency and perinatal care in the field of neonates and gastroduodenal care in the field of the elderly became widely apparent in society. This lawsuit involved a girl who had a tracheostomy surgery and died after being denied treatment by seven medical institutions in Tokyo, despite her complaints of being in a poor physical condition. Gastric bandages for the elderly emerged as a result of an incident in which a patient was cut off by a medical institution [32]. In July 2010, the MHLW established the "Study Group on the System for Implementation of Aspiration of Tannin by Care Workers, etc.," based on issues such as whether medical care should be positioned in the law rather than in operation of the law to prevent substantive illegality. Based on the discussions of the study group, the Social Worker and Care Work Law was partially amended in 2012. These revisions included Article 48, Paragraph 2, permitting care workers to perform sputum suctioning as authorized specified activities. Provisions were also added for non-care workers, such as helpers, teachers, and child-care workers, allowing them to engage in sputum suctioning under specific circumstances [33].

In response to these legal charges, MEXT issued guidelines entitled "Future Responses to Medical Care in Special Needs Schools" (December 20, 2011) [34]. These guidelines outlined scenarios where teachers or staff might perform sputum suctioning in special-needs schools (Figure 1).

This third period marked significant legal interpretations aimed at addressing "substantive illegitimacy," broadening the scope of care providers for children and persons with disabilities, and the elderly, and ultimately driving legislative reforms.

4. Fourth Period (2012-2015): The era of law-based responses

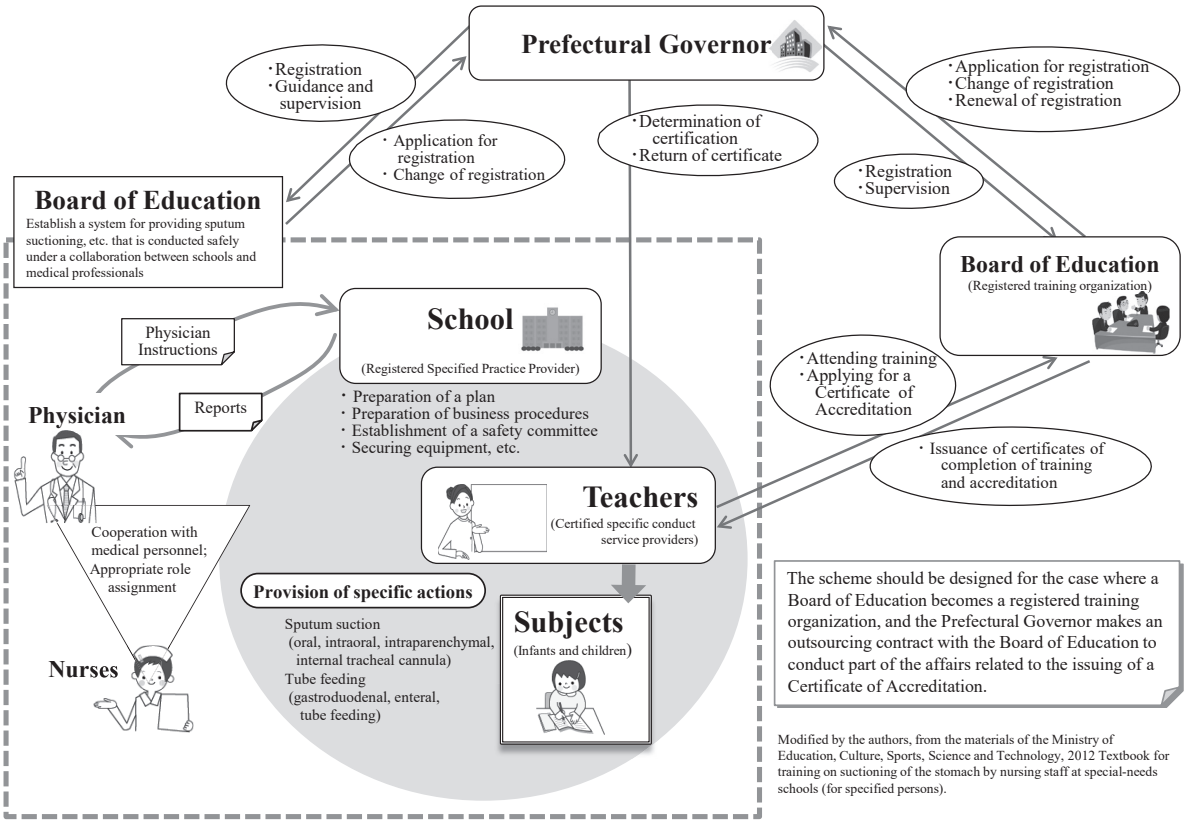


Figure 1. System of sputum suction, etc. in special-needs schools

Following the legalization of medical care in 2012, MEXT issued a notice providing guidance on implementing the new framework. However, as it constituted only technical advice under Article 245-4, Paragraph 1 of the Local Autonomy Law, it led to discrepancies in implementation across local governments.

During this period, the MHLW evaluated the "Comprehensive Support for Persons with Disabilities Act" three years after its enactment. The main findings were (1) Clearly defining the position of children requiring medical care within the support system for children with disabilities, even if they are not classified as severely mentally or physically handicapped; and (2) Promoting the provision of necessary support for these children to ensure their inclusion within the system [35].

5. Fifth Period (2016-2020): The ripple effect era of the ratification of the Convention on the Rights of persons with disabilities

In preparation for ratification of the UN Convention on the Rights of Persons with Disabilities (2014), Japan enacted the "Act on the Elimination of Discrimination on the Basis of Disability" in 2013, alongside partial revisions to the School Education Law Enforcement Order within the education sector. The MEXT highlighted challenges related to providing reasonable accommodation for children with disabilities, particularly in a report entitled "Results of the Survey on the Actual Conditions of Accompanying Children with Disabilities in School Life by Their Parents and Other Persons" (October 22, 2015) [36]. This report identified the continued reliance on parents accompanying children with disabilities in elementary and junior high schools as an issue. Consequently, in FY2016 funding to assign nurses to these schools was extended to include elementary and junior high schools.

In response to the 2015 "Review of the Comprehensive Support Law for Persons with Disabilities Three Years After Its Enforcement - Report of the Subcommittee on Persons with Disabilities of the Council on Social Security," the MHLW amended the Comprehensive Support Law for Persons with Disabilities and Child Welfare Law. Enacted on May 25, 2016 and promulgated on June 3, 2016, these amendments required local governments to make a "mandatory effort" to support children requiring medical care. In addition, they obligated the formulation of welfare plans for children with disabilities, prepared every three years over a five-year period. In the "Basic Guidelines for Ensuring Smooth Implementation of Disability Welfare Services, etc. and Daycare Support for Disabled Children," the MHLW stated, "In order for children with medical care to receive appropriate support, by the end of FY 2008, a forum for consultation should be established in each prefecture, region, and municipality to promote cooperation among organizations involved in health, medical care, welfare for persons with disabilities, childcare, education, etc [37]. Afterwards, each municipality began to set up a "forum for consultation" by establishing a children's subcommittee and a subcommittee for children with medical care in the existing Council for Services and Support for Persons with Disabilities, or by setting up a separate support council for children with medical care.

On June, 2016, the day when the partial revision of the Child Welfare Law (hereinafter referred to as the "Revised Child Welfare Law") went into effect, the "Notice on Further Promotion of Cooperation among Health, Medical Care, Welfare, Education, etc. concerning Support for Children with Medical Care" was issued. Furthermore, by the MEXT, the "Future Response to Medical Care in Schools (Notice)" (March 20, 2019) was issued by MEXT[38].

Meanwhile, in 2018, a lawsuit alleging violation of the Law for the Elimination of Discrimination against Persons with Disabilities, etc., and the Japan Federation of Bar Association's "Opinion on the Care and Education of Children Requiring Medical Care" (September 21, 2018) [39] were issued. Despite these developments, the revised Child Welfare Law mandated only an "obligation to make efforts," leading to persistent regional disparities in the support that was provided.

6. 6th Period (from 2021): Passage of the "Law for Supporting Children with Medical Care"

Despite the revisions to the Child Welfare Law and directives from MEXT, regional disparities in local government efforts persisted. In response, the Act on Support for Children under Medical Care and their Families was enacted in June 2021. This legislation specifically defines "children with medical care" as those requiring ongoing medical care—such as ventilator use or sputum suction—to sustain daily and social life. Notably, it also includes high school students aged 18 or older. The new law elevates support for these children from a "duty of effort" under the revised Child Welfare Law to a formal obligation and responsibility of both national and local governments. A key feature of the act is its emphasis on supporting families, as reflected in the inclusion of "support for families" in its title. The law also aims to prevent guardians from leaving their jobs due to the need to accompany their children to school or other activities (Figure 2).

The law stipulates the establishment of "support centers for children with medical care" in each prefecture to provide consultation and information in the community, as well as the enhancement of support in daycare centers and schools.

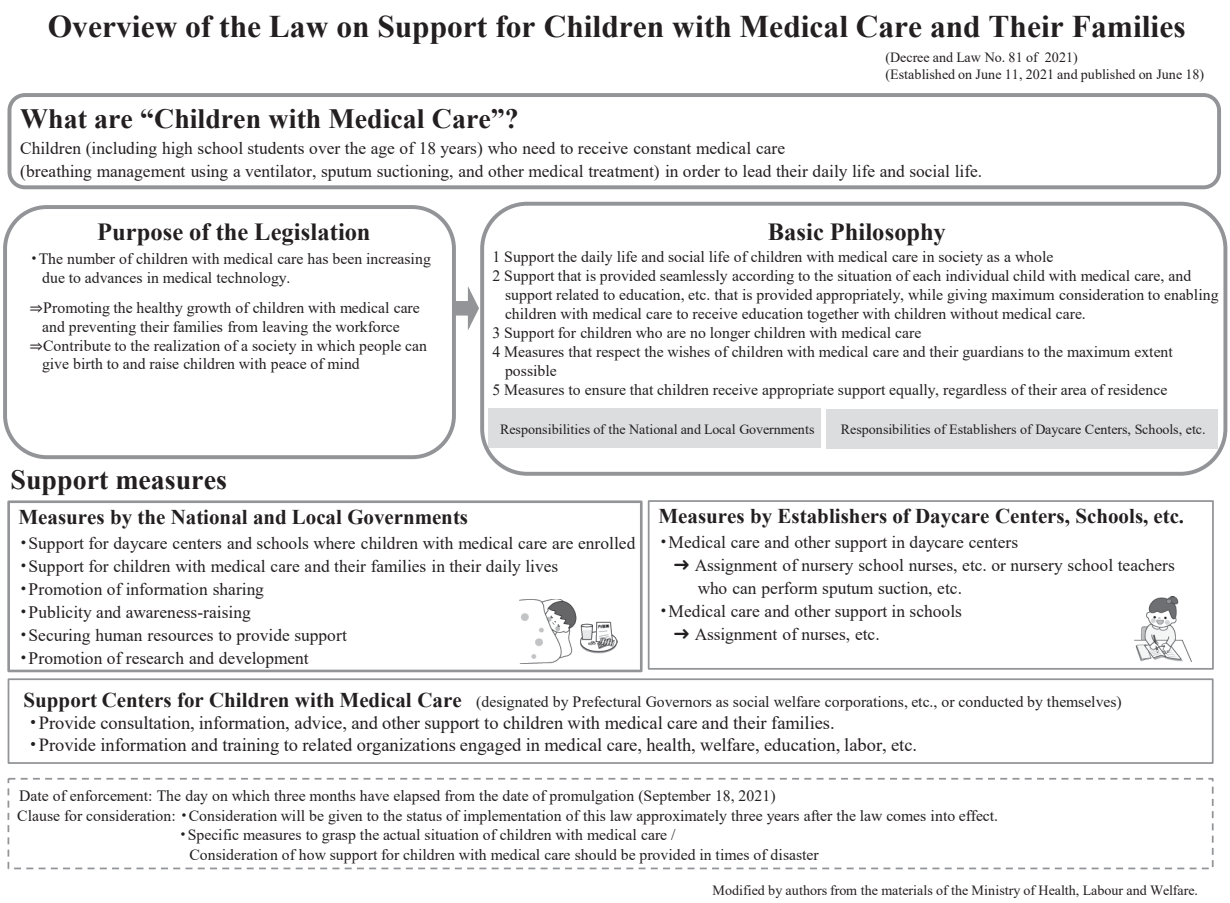


Figure 2: Overall picture of the Act on Support for Children with Medical Care and their Families

Local governments are currently promoting the "establishment of a forum for consultation among relevant organizations for the support of children with medical care" and the participation of family associations and concerned parties in the formulation of welfare plans for children with disabilities. Under these circumstances, the "National Medical Care Line (nicknamed 'Eye Line')" was established on March 27, 2022 [40] to realize the philosophy of the Law for Supporting Children with Medical Care, which supports the daily lives and social life of children with medical care throughout society, by fostering connections among children who require medical care, to their families, and supporters across Japan.

The above provides an overview of social, medical, welfare, and educational developments over the past 33 years, from 1988—when the issue of medical care in school education first emerged—to 2021, when the Law for Supporting Children with Medical Care was enacted. Notably, the five years between 2016 and 2021 saw heightened awareness of the challenges faced by children requiring medical care and their families, with increased coverage by the mass media. During this period, both national and local governments accelerated their efforts to address these issues. A pivotal force in this movement was the Nagatacho Council for Children's Futures [41]. The Council held its first meeting on March 15, 2015, as a nonpartisan initiative involving Diet members, government officials (from the Cabinet Office, the MEXT, and the MHLW), medical professionals, and non-profit organizations. The Council has worked consistently to design new systems and revise or expand existing frameworks to meet contemporary needs. Its efforts have culminated in two significant outcomes: (1) Revision of compensation for welfare services for persons with disabilities in FY2021; and (2) Enactment of the Law for Supporting Children with Medical Care. The Council's work to establish robust social welfare systems and improve their implementation exemplifies "social action." The activities of the Nagatacho Council for Children's Futures can indeed be regarded as a powerful example of social action, driving systemic change and fostering greater support for children requiring medical care and their families.

III. Changes and positioning of "medical care" and related terms

This chapter provides an overview of the terms and ac-

tions associated with medical care, such as suctioning of phlegm and tube feeding, focusing on their definitions, usage, and implications.

1. "Medical care" and related terms

(1) Medical practice

Table 2 summarizes the actions taken as medical practice by the Tokyo Metropolitan Board of Education.

(2) Medical care

The term "medical care" was first introduced in municipal documentation in 1991 in the "Report of the Study

Committee on Cooperation with Medical Care" by the Osaka Prefectural Board of Education. This report outlined medical care actions such as nasal tube feeding, sputum suctioning, urine collection, tracheostomy management, and oxygen inhalation.

Among medical professionals, this term was addressed in the "Symposium II QOL of Chronic Neurological Diseases in Children" at the 37th Annual Meeting of the Japanese Society of Pediatric Neurology in 1995 [42]. In 1998, the "Volunteer Doctors in Kanto Area Involved in Medical Care and Education of Children with Disabilities" and others [43] stated that the "targeted medical care activities" should include "medical care and assistance activities that are recognized as home medical care in insurance treatment and other medical life care and assistance activities that are conducted at home on a daily basis." The content of these acts include tube feeding, suctioning, insertion of airways, and urinary drainage.

The first-time medical care was mentioned in a document by the Ministry of Education was in the "Second Report on the Improvement and Enhancement of Special Education" (1997) [44] by the Council for Investigation and Research Cooperation on the Improvement and Enhancement of Special Education.

"Children requiring medical care" are described as "children with functional impairments in eating, swallowing, breathing, and excretion, who may require care such as tube feeding, sputum suction, and urine collection. These actions are performed by family members at home as daily nursing care, and are called "medical care" because they are different from the "medical care" for acute treatment purposes conducted in hospitals [45].

In Article 56-6, Paragraph 2 of the revised Child Welfare Law of 2016, a child in need of medical care is defined as "a child with disabilities who is wearing a ventilator or in other conditions requiring medical care to lead a daily life." Based on this, in 2017, the MEXT's "Project for Establishment of Medical Care Implementation System in Schools" began to express "advanced medical care," as "the enrollment of children who need medical care other than specified actions such as oxygen inhalation and ventilator management, is increasing at schools."

In the "Law for Supporting Children with Medical Care," Article 2, Paragraph 1 defines "medical care" as "respiratory management using a ventilator, sputum suctioning, and other medical treatments." Article 2, Paragraph 2 defines a "child with medical care" as a child who requires constant medical care to maintain daily and social life.

Specifically, Paragraph 2 states: "'Child with medical care'means a child for whom constant medical care is essential to lead a daily and social life." Although after the introduction of the term "advanced medical care," the phrase "medical care provided by nurses" has frequently appeared, considering the historical context in which the term "medical care" was created to describe care provided by non-medical personnel, this constitutes a misuse.

(3) Routine and emergency care

In the Model Project Study on Medical Care in Schools for the Disabled in around 2000, the Ministry of Education classified actions that teachers can perform as "routine and first aid" or "routine and emergency care." The details of such care are the following: 1) Suctioning above the pharynx; 2) Tube feeding by injecting through an indwelling tube in students who do not exhibit coughing, vomiting, wheezing, or other complications (excluding stethoscopic judgment of tube tip placement); 3) Assisting with self-purging; and 4) Self-liquidating urine assistance.

(4) Authorized specified conduct worker

According to Article 48-2 of the revised Social Worker and Care Worker Act of 2012 and Article 3 of the Supplementary Provisions, "specified acts" of sputum suctioning (nasal, oral, and tracheostomy cannula) and tube feeding (nasal, gastric, and intestinal) can be performed by health-

Table 2. Contents of Medical Practice

1988 Tokyo Metropolitan Board of Education Urinary	Urinary drainage, management of tracheostomy, suctioning of bedrock, oxygen inhalation, nasotracheal injection of food and water.
1989 Tokyo Metropolitan Board of Education Second Report	Tube feeding, respiratory support, suctioning, forced urination, management of artificial respiration apparatuses, oxygen inhalation, intubation.
1991 Report on the state of education for children and students requiring medical treatment	Tube feeding, management of tracheal cannula, suctioning of bedpans, urinary drainage, oxygen inhalation.

care workers and others who have received specific training to become "authorized specified act service personnel." The law enables nursing care workers, etc. to perform sputum suctioning, etc. as a medical assistant after undergoing training and receiving authorization.

2. Issues related to the concept of medical care and medical practice

(1) Items that are not, in principle, medical practice

In the process of establishing a system for caregivers to perform sputum suctioning, etc., a notice was issued in July 2005 to clarify the interpretation of medical practice. This was a list of actions that are often questionable in the field of nursing care for the elderly and disabled outside of medical institutions, and that are not, in principle, considered medical practice. According to this, "Assistance in self-purging," which was indicated as "routine and emergency treatment" that teachers can perform, is not a medical act and therefore does not need to satisfy the condition of inhibition of illegality [46]. In 2016, a notice was issued to inform the public and the field of nursing care for the elderly and disabled. In December 2022, a notice was issued in order to organize and make known the acts that are not considered to be medical acts, with a focus on acts that are considered to be frequently performed in nursing care settings, and to allow nursing care workers to perform those acts with peace of mind [47].

(2) Response to medical practice by prevention of substantive illegality

As described in "The Third Period (2005-2011)," on June 9, 2003, the Subcommittee on Support for Home Care of ALS Patients prepared a report, which interpreted the law as allowing non-medical personnel to perform suctioning of sputum, etc. if certain conditions are met [48]. The report stated that the law "effectively prevents illegality." The conditions for non-family members to perform suctioning of sputum" (conditions for prevention of illegality) include: 1) management of the medical care environment, 2) appropriate medical management of the patient or disabled person, 3) education for non-family members, 4) the relationship with the patient or disabled person (written consent), 5) appropriate suctioning of sputum in collaboration with doctors and nursing staff, 6) ensuring that there is an effective communication and support system for contact in the event of an emergency, and 7) the patient or disabled person's condition of being in a hospital or other medical institution.

This "preclusion of substantive illegality" also applies to cases in which the patient or his/her family members perform the injection. For instance, "It is not a violation of Article 17 of the Medical Practitioners Act if a physician, after providing sufficient patient and family education to a diabetic patient who is judged to require continuous insulin injections, instructs the patient (or family member) to self-inject insulin under appropriate guidance and management" [49]. Similarly, the utilization of automated external defibrillators (AEDs) in Japan was approved for utilization by airline flight attendants in December 2001 [50] and by the general public in July 2004 [51]. Other cases include EpiPen utilization in anaphylactic shock [52,53], suppositories for severe seizures in epilepsy [54], Bucolam® for severe seizures in epilepsy [55], and Baxmi® for severe hypoglycaemic attacks [56]. These are all included as a result of application of the "substantive illegality bar."

(3) Authorized specified acts (Social Worker and Care Worker Act)

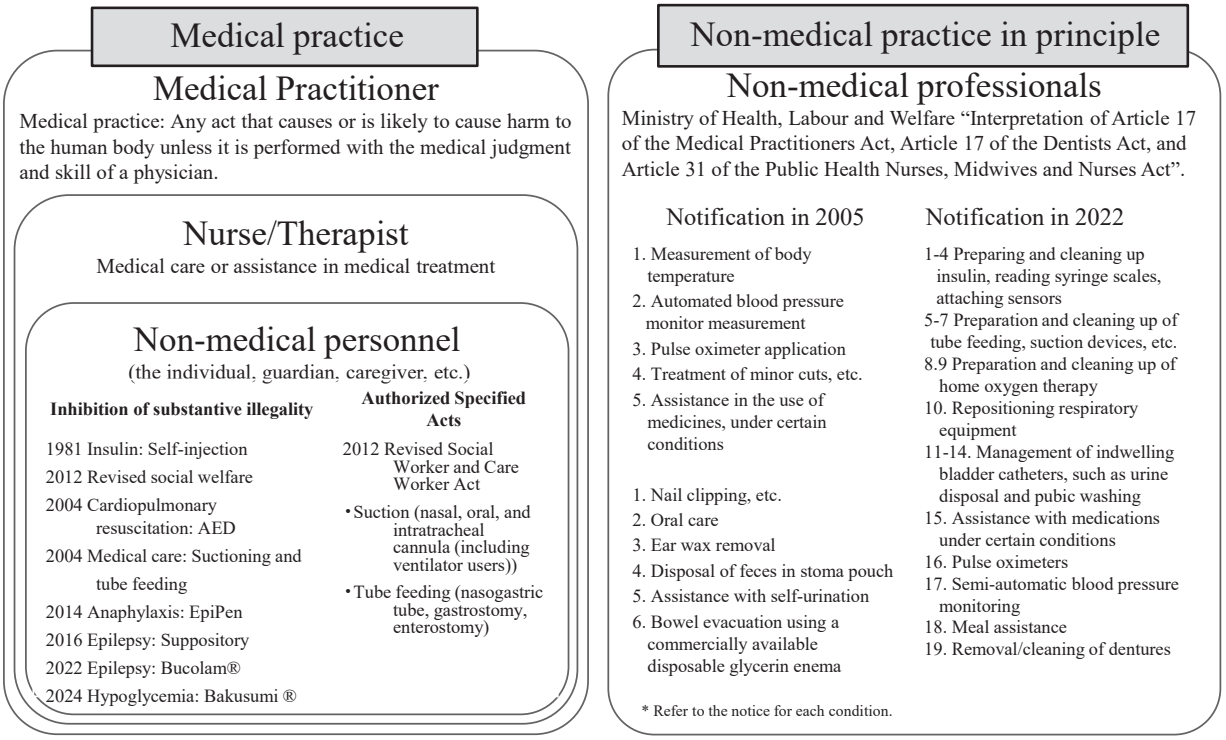
The "specified acts" authorized under the 2012 revised Social Worker and Care Worker Act are all medical acts. However, by having care workers undergo a certain level of training to become "authorized specified acts practitioners," they can "perform sputum suctioning as medical assistance," despite the provisions of Article 31, Paragraph 1 of the Health Nurse, Midwife and Nurse Act (exclusive duties of nurses). However, by receiving certain training and becoming a "certified specific action service provider," a nurse practitioner can "perform sputum suctioning as an aid to medical treatment."

(4) Conceptual diagram of "Medical Practice" and "Non-medical Practice in Principle"

"Medical Practice" and "Non-medical Practice in principle" are exhibited in Figure 3, which combines Article 17 of the Medical Practitioners Act, Article 31, Paragraph 1 of the Public Health Nurses, Midwives, and Nurses Act, and the aforementioned items. A "medical practice" is "an act that causes or is likely to cause harm to the human body unless it is performed with the medical judgment and skill of a physician. "Medical practice" includes 'medical care or assistance in medical treatment for an injured or sick individual,' which is the exclusive duty of nurses under Article 5 of the Public Health Nurses, Midwives, and Nurses Act.

In the case of physical therapists and occupational therapists who provide physical therapy and occupational therapy under the direction of physicians, Article 15 of the Physical Therapist and Occupational Therapist Act stipulates that they "engage in the business of providing physical therapy or occupational therapy as an aid to medical treatment. Similarly, Article 48-2 of the Social Worker and Care Worker Act and Article 3 of the Supplementary Provisions stipulate that nursing care workers "may engage in sputum suctioning as an aid to medical treatment. These articles partially remove the exclusive duties of nurses.

In the case of non-medical personnel, there are other responses based on the "substantive illegality preclusion." All



* Whether or not the act constitutes a medical practice, it is permissible for nursing staff to perform the act as an unavoidable measure for the time being should be determined on a case-by-case basis, taking into consideration the nature of the act, the patient's condition, and other factors.
Ministry of Health, Labour and Welfare, "Q&A regarding enforcement of sputum suctioning services (Part 4)" (February 24, 2012)

Figure 3. Conceptual diagram of "medical practice" and "non-medical practice in principle

of these are considered to be within the category of medical practice. Conversely, the MHLW has issued a notice on the category of non-medical acts in principle.

Although the MHLW states that, "Whether or not an act constitutes a medical practice and whether or not it is acceptable for a nursing staff member to perform the act as a measure that is unavoidable at the current time, should be determined on an individual basis, taking into consideration the manner of the act, the patient's condition, etc" [57], it is important to understand that these acts are highly individualized and cannot be clearly classified.

IV. Future prospects

The enactment of the Law for Supporting Children with Medical Care represents a significant step toward advancing welfare, education, and social systems for children requiring medical care. The infant mortality rate in Japan is one of the lowest among OECD countries, and the number of children to be helped will continue to increase [58]. However, a substantial gap remains between the ideals outlined in the law and the reality faced by families.

Many families experience frustration over the lack of practical implementation and infrastructure despite the legal provisions, while also recognizing the potential for change that the law brings.

Although the concept of home-based medical care was introduced in 1992 with the establishment of the home nursing system, many key environments—such as day-care centers, child development support facilities, schools, and daily living care facilities—are not formally recognized as venues for providing medical care. Article 1 of the Ordinance for Enforcement of the Medical Care Act narrowly defines "home, etc." as including private homes and residential facilities for the elderly. This limitation is evident in the fact that, even when nurses are assigned to day- care facilities, instructions from attending physicians are not covered by insurance, leaving families to bear the full cost.

To address this limitation, it is critical to broaden the scope of home-based medical care to encompass day-care facilities and similar settings. Establishing a support system that integrates cooperation across medical, welfare, education, and administrative sectors is essential for ensuring a richer and more inclusive community life for children with medical care and their families. Throughout this process, the voices and experiences of families must be prioritized.

Despite the law's enactment, public awareness and understanding of children with medical care remain limited.

Many individuals still associate such children exclusively with hospital settings or severe illness. Moving forward, efforts must focus on raising the social recognition of children with medical care, which will enable their families to enjoy more integrated community lives. In addition, a robust coordination system and improved resources are needed to support these families effectively.

Conflicts of Interest

The authors declare that there are no conflicts of interest.

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＜総説＞

日本における医療的ケア児支援法制定に至る歴史的沿革と今後の展望

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抄録

「医療的ケア児及びその家族に対する支援に関する法律」が 2021 年 6 月 11 日に成立したが，学校教育で痰の吸引や経管栄養などが必要な児童生徒の対応の課題が顕在化したのは 1988 年であった．この間，文部科学省や厚生労働省の施策の中で，こうした行為について，医療職でない者が行う法解釈として，実質的違法性阻却，改正社会福祉士及び介護福祉士法による認定特定行為，原則として医行為でないものなどが示されてきた．あわせて，法施行後の地域生活における課題を整理し，今後の展望を示す．

キーワード：医療的ケア児及びその家族に対する支援に関する法律，医療的ケア，医行為，実質的違法性阻却，認定特定行為，原則として医行為ではないもの