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"Legal Research Related to Medical Practice"

Report

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Survey Research on Legal Precedents, Etc., Regarding Medical Accidents in Medical Practice

1. Objectives of the Survey

○ The report of the National Council on Social Security System Reform (August 6, 2013) stated that in order to address the issue of the shortage of physicians, in view of the current situation in which physicians are performing duties other than those that can only be performed by a physician, the duties of physicians and nursing duties should be urgently reviewed.

○ The report of the Ministry of Health, Labour and Welfare Social Security Council Healthcare Committee (December 27, 2013) stated that medical acts currently performed by nurses which require advanced and specialized knowledge and decision-making should be positioned as *tokutei-no-koi* ("specific medical practices") (hereinafter referred to as "specific medical practices") and that consideration of a system whereby nurses who have completed their training can perform specific medical practices in accordance with procedure manuals on patients specified by a physician (hereinafter referred to as "the system" should be carried out.

○"Legal Research Related to Medical Practice and Healthcare Professions" (1989 Health Science Research Report; hereinafter referred to as "Legal Medicine Research") identified the issue that "consideration needs to be given to the appropriate apportionment of responsibilities in parallel with the division of duties amongst physicians and other healthcare professionals in the future with the expansion of team medical care", and it is therefore necessary to examine the legal responsibility of physicians and nurses, which is an issue for the operation of the system.

2. Premise of the Survey

○ The system presupposes directives issued in a different form than physicians giving nurses instructions on a case-by-case basis. In concrete terms, medical institutions prepare a procedure manual in advance, physicians determine the feasibility of applying the system based on the patient's medical condition, and if feasible, a nurse who has completed his/her training checks the patient's medical condition against the pathology prescribed in the procedure manual and carries out the specific medical practices. Furthermore, the specific medical practices require advanced and specialized knowledge and decision-making with regard to medical assistance.

○ In order to examine the legal responsibility of physicians and nurses, it is necessary to survey legal precedents related to medical safety. In order to obtain the knowledge that should used as a reference with regard to operation of the system, rather than simply exhaustively surveying past legal precedents premised on previous systems, here it was decided to focus the survey on representative legal precedents and theories that show general thinking and concepts concerning legal responsibility.

○ Of the legal precedents related to medical safety, etc., to enable to enable the findings to be used as a reference with regard to operation of the system, the survey focused on legal precedents in which (i) the scope of medical activities or medical assistance activities was a point of contention; (ii) the manner in which a physician gives instructions was a point of

contention; or (iii) the negligence of a nurse was a point of contention.

3. Points to Consider Regarding Criminal/Civil Actions

○ In interpreting legal precedents, it needs to be noted that there are differences between criminal and civil actions in purpose, burden of proof, and the decree of proof required. In concrete terms, the purpose of criminal actions is for the state to impose a penalty on those who carry out illegal activities and restore social order; for this reason, in criminal trials the prosecutor assumes the burden of proof, and an extremely high degree of proof is required. By contrast, in civil actions trials are conducted from the perspective of determining who is responsible for damage that has occurred, the extent to which they are liable, and what would be a fair resolution of the situation. The plaintiff can decide against whom they wish to bring a suit—the medical institution, physician, nurse, etc.—and because the burden of proof is on the plaintiff, who has no authority to conduct a criminal investigation, the degree of proof sufficient for establishing a causal relationship is a high degree of probability, and so the burden of proof is reduced. (October 24, 1975 decision of the Second Petty Bench of the Supreme Court, etc.).

4. Results of Survey on Legal Precedents, Etc.

(1) The Significance of Medical Standards and Scope of Duties as Standards for Determining the Presence or Absence of Negligence

○ In determining the presence or absence of negligence, "what should generally be the standard for duty of diligence is the medical standards being implemented at the time of the medical treatment in so-called 'clinical medicine'". (January 23, 1996 decision of the Third Petty Bench of the Supreme Court, Supreme Court Decisions for Civil Actions Volume 50 No. 1 p. 1; also the March 30, 1982 decision of the Third Petty Bench of the Supreme Court, Supreme Court Cases Civil No. 135 p. 563, and the January 19, 1988 decision of the Third Petty Bench of the Supreme Court, Supreme Court Cases Civil No. 153 p.17, which were referenced in the aforementioned decision). Accordingly, with regard to specific medical practices also, the standard for determining the presence of absence of negligence is whether or not the medical standards at the time of the treatment were met. Although nurses should of course complete the necessary training, even if they have completed their training, for example, they are required to continue to maintain their skills to ensure they are able to meet the current medical standards.

○ Furthermore, it should be noted that, under the Medical Practitioners Act and the Act on Public Health Nurses, Midwives and Nurses, the actions that a nurse can generally carry out lawfully and the handling of the actions of the nurse in question as part of his/her duties with regard to civil or criminal liability are two entirely different issues. In the latter case, it is sufficient if the action outwardly appears to be part of the nurse's duties, and there is no practical screening to ascertain whether or not the actions were within the scope of the nurse's usual duties.

○ "Legal Medicine Research" explains that "of all medical practices, those that are so high-level

and dangerous that they must always be performed by a physician (or dentist) are called 'absolute medical practices' and all other medical practices are called 'relative medical practices'. Whether or not it is possible for relative medical practices to be carried out by a healthcare professional other than a physician is determined by a physician who takes into consideration the capabilities of the healthcare professional. However, there are also theories that question the necessity of making this distinction."

○ With regard to medical assistance activities, interpretations have been provided in past government notifications individually for administering intravenous injections and anesthesia, but within the scope of medical assistance activities that can generally perform individually, the reality is that physicians in the workplace determine what activities nurses can perform based on the medical standards at that time and individual nurses' skill levels.

○ With regard to this point, it is believed that the scope of medical assistance activities would become clearer to a certain degree than they have been thus far if the scope of specific medical practices were indicated through the issue of government notifications under the system.

○ Furthermore, with regard to the scope of duties of medical professions prescribed as an exception to the monopolization of duties by nurses in medical assistance activities under the Act on Public Health Nurses, Midwives and Nurses, it is legally interpreted that nurses can also likewise perform these duties.

【Reference 1】

With regard to intravenous injections, a notification issued by the director of the Ministry of Health and Welfare Medical Affairs Bureau in 1951 stated that "Due to the fact that intravenous injections exert an enormous impact on the body as the result of the vascular infusion of drugs and are technically difficult to perform, they should be performed by a physician or dentist and are understood to exceed the scope of the duties of nurses prescribed under Article 5 of the Act on Public Health Nurses, Midwives and Nurses. Accordingly, intravenous injections are outside the scope of application of Article 37 of the Act. In the case that a nurse performs an intravenous injection as part of his/her duties, this action is in violation of Article 17 of the Medical Practitioners Act" (Note: words have been added in part and the names of occupations changed to their current titles). Subsequently, in accordance with the purport of the interim report of the "Investigative Commission on New Nursing Styles" issued in September 2002, intravenous injections were included within the scope of medical assistance activities under "Administration of Intravenous Injections by Nurses, Etc." (2002 Health Policy Bureau Release No. 0930002).

In contrast, with regard to the application of Article 211 of the Criminal Code regarding professional negligence and involuntary manslaughter, on page 1432 of the High Court Decisions Volume 5, No. 9 (Nagoya High Court, Kanazawa Branch, Decision of June 13, 1952) it is stated that "It should be interpreted that, as medical assistants within the scope instructed by the attending physician as prescribed under Articles 5, 6, and 37 of the Act on Public Health Nurses, Midwives and Nurses, Nurses are permitted to carry out procedures that can be

performed by physicians such as using medical equipment on patients, administering drugs, or issuing instructions on the usage of drugs, and therefore it must be said that administering intravenous injections under the instructions of physicians is naturally within the scope of nurses' duties." Furthermore, on page 2608 of the Supreme Decisions for Criminal Actions Volume 7, No. 13 (December 22, 1953 decision of the Third Petty Bench of the Supreme Court)—the appeal hearing for this case—it is stated that "in the case that a patient dies or is injured due to negligence when a nurse administers an intravenous injection under the direction of a physician, they must assume responsibility in accordance with Article 211 of the Criminal Code.

【Reference 2】

With regard to the administration of anesthesia, according to a notification issued by the director of the Ministry of Health and Welfare Medical Professions Division in 1965, (i) "Because the administration of anesthesia is a medical practice, carrying out any process in the administration of anesthesia by any person who is not a physician, dentist, nurse, assistant nurse, or dental hygienist under the direction of a physician or dentist as part of their duties is prohibited under the Medical Practitioners Act; Dental Practitioners Act; Act on Public Health Nurses, Midwives and Nurses; and Dental Hygienists Act"; (ii) "It is in violation of the Medical Practitioners Act for a nurse to exceed the scope of medical assistance and administer anesthesia as part of his/her duties"; and (iii) "In the case that there is a question, in situations where in practical terms there are no instructions from a physician or it is considered to be ordinarily impossible to receive instructions from a physician, it is in violation of the Medical Practitioners Act and the Act on Public Health Nurses, Midwives and Nurses for a person who is not a physician to administer anesthesia.

【Reference 3】

Under the Emergency Life-Saving Technician's Act, as an exception to the monopolization of medical assistance duties by nurses under the Act on Public Health Nurses, Midwives and Nurses, emergency live-saving technicians (paramedics) may perform tracheal intubation on patients in cardiopulmonary arrest as part of their duties in accordance with the comprehensive instruction of a physician under the medical control system. Furthermore, under the Clinical Engineers Act, as an exception to the monopolization of medical assistance duties by nurses, clinical engineers may operate life support management equipment as part of their duties, but as mentioned above, legally it is understood that nurses can also perform the same actions as part of their medical assistance activities.

(2) How Physicians Issue Instructions and Legal Responsibility

○ With regard to instructions issued by physicians, it is understood that "an instruction must not necessarily be issued in written form, but whether or not an instruction in whatever form

should be understood to be an instruction under the said article (Note: Article 37, Act on Public Health Nurses, Midwives and Nurses) can only be determined on a case-by-case basis in specific cases" (notification issued by the director of the Ministry of Health and Welfare Medical Affairs Bureau in 1951: "Question Regarding Article 17 of the Medical Practitioners Act").

○ Legal Medicine Research states that "with regard to accidents that occur in medical practice, in the past, even in the case that the procedure was performed by a healthcare professional under the direction of a physician, the physician who supervised the procedure bore the majority of criminal and civil liability." However, the number of legal precedents stating that nurses should bear responsibility together with physicians is increasing.

○ It has been observed that "whether or not nurses should be held responsible separately and independently from physicians in the case of nursing accidents depends on the degree of independence of nurses in carrying out their nursing duties"[1] and that "due to the progression of division of labor and collaboration in healthcare with the promotion of team medical care and the increasing expansion of the role of nurses in home medical care, the responsibility of nurses will no doubt come to be understood as being separate and independent from the responsibility of physicians and hospitals."[1]

○ Furthermore, as with physicians, nursing liability insurance for nurses exists, and so the is also scope for seeing that the concept that it is possible for nurses to independently be held liable for a medical accident is becoming socially established.

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[1]Kanno K. Theory of Legal Precedents for Nursing Accidents. Shinzansha, 1997 (in Japanese)

Case Examples in which a Nurse Was Penalized for Professional Negligence Resulting in Death

【Case Example 1】 Professional Negligence Resulting in Death: Kagoshima Summary Court (informal hearing) ; not listed in the July 23, 2007 casebook; 500,000 yen fine.

At around 16:38 on April 30, 2001, at a certain hospital, a nurse was administering an intravenous drip containing xylocaine—an antiarrhythmic agent—to Patient A (a 5-year-old boy). There is a risk of xylocaine causing cardiac arrest or other severe medical conditions if administered too quickly and the attending physician had also instructed the nurse to administer the xylocaine solution at a rate of 5ml/hr. Immediately prior to the incident, the Patient A had been receiving another drug solution administered at a rate ml/hr, and so the nurse had the duty of diligence to change the administration rate by appropriately adjusting the syringe pump, which was the apparatus for setting the administration rate before administering the xylocaine solution; despite this, however, the nurse failed to change the administration rate setting, and so from around 16:38 until around 16:47 on the same day, the patient was administered with the xylocaine solution at a rate of 80ml/hr, causing his heart and lungs to stop temporarily, resulting in hypoxic ischemic encephalopathy. Subsequently, the patient died of multiple organ failure due to hypoxic ischemic encephalopathy on November 20, 2002 at Hospital X in Kagoshima City.

【Case Example 2】Professional Negligence Resulting in Death: Yawatahama Summary Court (informal hearing); not listed in the July 23, 2007 casebook; 500,000 yen fine.

In a ward of a certain hospital at around 17:43 on June 23, 2006, a nurse was instructed by Doctor B, the attending physician for Patient A (a 63-year-old man), to administer 40ml of potassium chloride preparation to Patient A. Because administering this preparation too rapidly can cause hyperkalemia with serious side-effects such as cardiac arrest, the nurse had the duty of diligence to dilute the potassium chloride preparation before administration by intravenous drip in accordance with the directions for use for the preparation, or to dilute the potassium chloride preparation by injecting it into the high-calorie nutritional solution already being administered to Patient A via a drip inserted into his vein as the nurse was instructed to do by Physician B, as well as to comply with the instructions of Physician B regarding administration methods. Despite the duty of diligence to dilute the potassium chloride preparation by injecting it into the high-calorie nutritional solution already being administered to Patient A via an intravenous drip, the nurse neglected to do this and instead rapidly administered 40ml of potassium chloride preparation unthinkingly via the side tube attached to the intravenous drip without first diluting the preparation by injecting it into the high-calorie nutritional solution already being administered to Patient A via an intravenous drip. As a result, at around 22:12 on the same day in the same ward, Patient A developed hyperkalemia and died from acute cardiac failure.

【Case Example 3】Professional Negligence Resulting in Death: Kanazawa Summary Court

(informal hearing); not listed in the September 3, 2007 casebook; 500,000 yen fine.

The nurse was working in a hospital performing such duties as providing care for injured and ill patients and assisting in medical procedures. At the hospital at around 15:00 on July 11, 2004, the nurse was injecting a nutritional solution into the stomach of Patient A (a 72-year-old man)—who was hospitalized due to cerebral infarction—via a feeding tube inserted from the patient's nasal cavity via the esophagus to the stomach. Patient A's cough reflex was impaired due to paralysis on his right side. In the case that the feeding tube is accidentally inserted into the trachea and nutritional solution is injected into the trachea without the mistake being realized, there is the risk of the patient dying from asphyxiation due to obstruction of the airway. For this reason, the nurse had the duty of diligence to pass air through the feeding tube after insertion and listen for the sound of air bubbles in the stomach fluid using a stethoscope or use another method for checking to ensure that the tube has been inserted into the stomach, and only then to inject the nutritional solution. However, the nurse failed in this duty of diligence by relaxing their caution due to the patient's weakened cough reflex. Although the nurse passed air through the feeding tube after insertion, they did not listen sufficiently for the sound of air bubbles in the stomach fluid and did not check to ensure that the tube had been inserted into the stomach. Without realizing that the tube was mistakenly inserted into the trachea, the nurse then unthinkingly injected approximately 400ml of nutritional solution from around 15:00 until around 17:30 into the trachea. This obstructed the patient's airway, and he consequently died of asphyxiation at around 22:57 on the same day.

5. Situation in the United States

The system differs from the so-called "nurse practitioner" system in the United States; under the Japanese system, nurses carry out medical assistance activities strictly under the direction of physicians, but the debate regarding the system stems from comments from the Council for Regulatory Reform and the Council on Economic and Fiscal Policy that in reviewing the division of roles between physicians, nurses, and other medical professionals, consideration should be given to introducing the American nurse practitioner system.

A summary of the history and current situation of American's specialist nurse system is therefore provided below.

○ American's so-called specialist nurse system (hereinafter referred to as "specialist nurses") is a system by which nurses can acquire certification for the following four roles.[2]

(i) Certified registered nurse anesthetist (CRNA)

A registered nurse who can administer anesthesia as part of his/her nursing duties.

(ii) Certified nurse-midwife (CNM)

A registered nurse who has undergone both nursing and midwifery education.

(iii) Clinical nurse specialist (CNS)

A registered nurse who is a specialist in a specialized field, area, or disease.

(iv) Certified nurse practitioner (CNP)

A registered nurse who has undergone education and practical training regarding the provision of a wide range of medical services, such as preventative and acute-phase medicine; a CNP checks patients' medical histories, carries out tests, and treats many commonplace acute or chronic diseases. Their duties also include interpreting radiograms and issuing prescriptions.

○ In the United States, because the Federal Constitution does not specify an authority regulating nurses, it is believed that the Congress cannot create legislation regarding the regulation of nurses. Consequently, regulation of nurses is currently the responsibility of each individual state. In concrete terms, each state legislature protects public health based on welfare authority (police power) and creates its own legislation establishing the position of nurses as specialists.[3]

○ The regulation of nurses began in 1903 in the State of North Carolina, which introduced a system for registering nurses. Subsequently, in 1938 the State of New York was the first in the country to define the scope of nursing duties (the practice of nursing), but the birth of specialist nurses predates this history. The history of specialist nurses began in 1860, during the Civil War, when nurses administered anesthesia during surgical operations. Since then, debate has continued in all states regarding the regulation of specialist nurses.[4]

○ Although the situation in the Unities the States differs from state to state, nationwide common model for specialist nurses (Consensus Model for Advanced Practice Registered Nurse, APRN Regulation) was published in 2008 by the National Council of State Board of Nursing, whose membership comprises the nursing associations of each state.[5]

○ The nationwide common model for specialist nurses attempts to introduce a nationwide

uniform regulation standard for regulating specialist nurses, who are operating under standards that differ from state to state. Created by 48 nursing organizations, this model lists as conditions that all specialist nurses must fulfill university level education, a federal-level certification system, licensing and regulation by state nursing associations, title monopolization, and recognition of training programs at the federal level.[6]

○ The nationwide common model for specialist nurses was drawn up because of concerns that the differences in regulations from state-to-state were confusing for patients as well as other medical professionals and posed a risk to medical safety.[7] For example, not only do the requirements for conferring a certain title differ from state to state, but also there are also discrepancies in regulations regarding prescriptions, so that a nurse can write a prescription in one state but not in another.[8]

○ Moreover, having acquired the education and practical training necessary for providing a certain level of medical care does not necessarily mean that specialist nurses are carrying out medical procedures. It seems that under special conditions, such as when there are insufficient physicians or there is no physician, it is possible for nurses to provide medical treatment,[9] and this point is extremely important.

○ In 2009, the World Medical Association (WMA) adopted the WMA Resolution on ask Shifting. This resolution notes in part that, while task shifting may be necessary under certain circumstances, it is accompanied by considerable risks. The greatest risk is the risk of lowering the quality of patient care. It is noted that, when medical judgments or decisions are being changed, not only do patients receive care from healthcare professionals with a low level of training, but also contact between patients and physicians decreases, services become fragmented and inefficient, appropriate follow-up is not carried out, incorrect diagnoses are made and incorrect treatments provided, medical personnel cannot treat complications, and various other problems related to the lowering of healthcare quality arise. In the system which Japan is about to introduce, thorough care also needs to be taken with regard to this point to ensure that the quality and sustainability of healthcare and the safety of patients are not lost due to the introduction of task-sharing.

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[2] O'Grady ET. Advanced Practice Registered Nurses: The Impact on Patient Safety and Quality. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 43. Available from: http://www.ncbi.nlm.nih.gov/books/NBK2641/

[3] Kathleen A. Russell. Nurse Practice Acts Guide and Govern Nursing Practice. Journal of Nursing Regulation. 3(3) Oct. 2012, pp. 36-73

[4] *Ibid.*, p. 37

[5] National Council of State Board of Nursing. The Consensus Model for APRN Regulation: A Consumer Guide. 2010, pp. 2

[6] *Ibid*

[7] *Ibid*

[8]See, for example, Phillips, Susanne J. 25th Annual Legislative Update: Evidence-based Practice Reforms Improve Access to APRN Care. Nurse Pract. 2013 Jan 10; 38(1):18-42. doi: 10.1097/01.NPR.0000423380.32036.33.

[9] National Council of State Board of Nursing. The Consensus Model for APRN Regulation: A Consumer Guide. 2010, pp. 2

6. Discussion

○ The legal precedents surveyed in [4.] above are based on the previous medical jurisprudence system. While specific medical practices have yet to be legislated, the following is a discussion of the points to which care should be given when operating the system, using past legal precedents and the situations in other countries as references.

○ In operating the system, the points at issue are (i) To which patients should procedure manuals be applied? (ii) Is the content of procedure manuals sufficient for nurses to be able to made decisions? And (iii) can nurses correctly understand the content of physicians' instructions (content of procedure manuals) and carry out specific medical practices? In accordance with these discussion points, we consider the legal responsibility of physicians, nurses, and medical institutions.

(Responsibility of Physicians)

○ The decision as to whether or not the procedure manual can be applied to a patient is included in the instructive actions of physicians and is an item that can only be performed by a physician. In the case that the decision to apply the procedure manual is itself incorrect, it is thought that the physician should bear responsibility.

○ Up until now methods for conveying physicians' instructions have included verbal or written notification, and even in the case that a procedure manual is used, it is imperative that the instructions be as clear as if they were being conveyed verbally or in writing.

○ When physicians give nurses instructions for specific medical practices, the physician must determine whether or not the nurse in question has the skills necessary for carrying out the specific medical practices in question. Such individual decisions are necessary even when the nurse in question has completed training and can lawfully carry out the specific medical practices in question under the Act on Public Health Nurses, Midwives and Nurses (see [4(1)].)

○ In order to ensure medical safety, it is thought that physicians need to establish a system for responding appropriately in emergencies in issuing instructions in preparation for changes in the patient's medical condition, etc.

(Responsibility of Medical Institutions)
○The system requires all medical institutions to prepare procedure manuals in advance. Medical institutions are thought to have the duty of diligence to ensure medical safety, and the management system must be thorough in order to ensure that medical safety is not impaired due to problems with procedure manual content.
○ With regard to procedure manuals, while it is of course necessary to ensure that duty of diligence standards of the normal medical workplace by, for example, clearly stating the measures to be taken in the event of a contingency situation, but in addition, in recent years there have been many situations in which physicians and various other medical professionals have worked together to provide medical treatment in the form of team medical care. From the standpoint of ensuring medical safety, even if procedure manuals are used, medical institutions need to notify their relevant medical personal about procedure manuals or team medical care systems utilizing procedure manuals in order to achieve the same degree of communication amongst medical professionals as previously.
○ Although nurses who have not completed their training can also perform specific medical practices under the specific instructions of a physician (not using a procedure manual), in such cases, from the perspective of medical safety it is thought that medical institutions need to provide nurses with opportunities for the required training and then check the skills of the nurses in question.

(Responsibility of Nurses)
○ Even in cases where a physician has determined the medical condition of a patient and instructed the nurse to provide care based on the procedure manual, if the patient's condition changes suddenly and it becomes difficult for the nurse to carry out the specific medical practices alone, the nurse is thought to also have a high duty of diligence to make the decision to receive further instructions from the physician, etc.
○ Furthermore, specific medical practices are actions requiring advanced and specialized knowledge and decision-making, and are thought to demand a higher medical standard than so-called general medical assistance activities. For this reason, with expansion of the role of nurses who have completed training, it is anticipated that there will be an increasing trend towards nurses sharing the burden of responsibility.