Legal Protection for Consumers of Nitrogen Gas Users (Case Study of Inefficient Medical Gas)

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Abstract—Nitrogen is gas-shaped chemical element, symbolized with the letter N and its atomic number is 7. Nitrogen is colorless, odorless, flavorless gas, as well as diatomic gas which is difficult to react with other elements or compounds, forming Nitrous Oxide Medical Gas (N2O), in the medical field is used as Analgesic (pain relief), Anaesthesia (measure to relieve pain while performing surgery), used by the surgeon for cryosurgery and cryobiology. The switch of N2O tube with CO2 on the anaesthetic machine that occurred in a hospital in Bengkulu in 2001 that led to the death of a patient, who underwent the right leg bone surgery due to broken leg. The medical staff's fault clearly did not apply the customer protection right and by violating the comfort and safety rights. The consequence is the medical providers must be responsible, based on the Regulation of the Minister of Health number 4/2016 on the usage of medical gas and medical vacum on the health service facility and the Decree of the Minister of Health number 1439/2002 on the usage of medical gas on the health medical service, profession standardization, medical gas operational standard procedure.

Keywords—medical gas, consumer, standard.

I. INTRODUCTION

Nitrogen as a chemical element, mainly exists in the open air is the fifth element that is abundant in the universe, it is estimated about 78% of the atmosphere, in the universe, it contains approximately 4000 trillion ton of gas. Nitrogen is available from liquid air through fractional distillation process, used as medical gas in medical service. Nitrogen gas (N2) is utilized for anaesthesia as well as during the tumor surgery, commonly known as cryosurgery, a measure that uses a small device to freeze tumor. When the device is successfully inserted, the device will release liquid nitrogen, temperature approximately -196°C. It functioned to freeze tumor and kill cancer cell. At the moment, the use of Nitrogen gas for tumor case in the brain is being developed. Meanwhile, cryobiology is the branch of science that deals with the study of life under low temperature conditions. The word is derived from a Greek word cryo that means cold, bios that means 'life' and logos meaning 'science'. Nitrogen medical gas has also an important role in many fields such as hospital, food industry, oil industry, workshop, vehicle tires, and so on.

The function of liquid Nitrogen gas (-196 °C), especially in the medical field namely: 1. To freeze and keep blood, sperm, embryo, bone marrow cell, and other live tissue samples in the long period; 2. To be used in the skin treatment or dermatology, such to burn warts and small benign tumor and other contagious skin abnormalities; 3. Has an important role in DNA molecule synthesis; 4. Inhaling liquid Nitrogen in gas or other forms will cause chest tightness.

Every time a person breathes, he will take some various gas contents, one of them is Nitrogen, the following is the gas content present in the air:

1. 1% Water Vapor and other gasses – released up to 250 times faster than Nitrogen
2. 21% Oxygen – released 3-4 times faster than Nitrogen
3. 78% Nitrogen – The largest molecule in the air, dry, non-flammable

The dangers of Nitrogen for the health of the human body include: 1. Make the body in the lack of vitamin A intake; 2. Nitrogen reactions with hemoglobin in the blood can cause the oxygen carrying capacity in the blood to decrease; 3. Nitrogen gas can form Nitro Amine as one of the most common causes of cancer; 4. Low down function of the thyroid gland, where the thyroid serves to change the intake of the body becomes energy

II. DISCUSSION

How to Legal the Protection for Consumers of Nitrogen Gas Users (Case Study from the Nitrogen gas tube mis-replacement event at the hospital). The case was the misreplacement of N2O tube with a tube containing CO2 gas on the anesthetic machine, caused the patient of post-surgery of the right leg bone was experiencing a breathing problem. Due to the influx of CO2 gas into the blood, the patient is unconscious, then the patient is treated continuously in the room intensive care with the help of respiratory engine (ventilator), and eventually died. In the case of medical gas tube mis-replaced by the officers caused a huge loss, so this case should be studied comprehensively, whether the actions of officers who are not meticulous can be summed up as a form of negligence? Or is this a case of malpractice (criminal)?

III. STUDY

The choronology of the medical gas tube switch began when the patient had broken right leg. The orthopedic doctor later planned a bone surgery on the broken leg after performing physical and other supporting tests. It was
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concluded that the patient was in good condition and suitable for surgery. Anesthesia was done before surgery, it aimed to make the patient felt numb. The anesthesia procedure was done by anesthetist doctor, while the surgery was done by the orthopedic doctor. Therefore, the surgery included two experts of different field of works, in addition some paramedics working in the operating room.

The report said that the surgery went well, the broken bone position has been repositioned to its initial condition. However, suddenly the patient was so difficult to breathe, that he became unconscious. Later, the patient was transferred to ICU to be treated intensively to help the patient breathe, the ventilator was installed.

The investigation of the case found that there was a mistake in installing anesthetic gas (N₂O) on anesthetic machine. N₂O was supposed to inserted in the tube, instead CO₂ was installed. The use of CO₂ gas is for different surgery, namely cataract. The infiltration of CO₂ into blood flow caused respiratory distress so that the oxygenation process was disturbed, later the patient became unconscious and passed away. The switch of anesthetic tube at the operation room is a routine activity, so that it should be a normal one. When a medic gas tube is to be changed, the paramedics will understand about the tube identification and all that associate with its use. In other words, there is a failure by the paramedic in the replacing process of anesthetic gas in the operating room. The question is whether the hospital has a service standard, profession standard, standard operating procedure (SOP) of security, gas use and installing gas tube to the anesthetic machine.

The regulation of the Minister of Health, the procedure must be equipped by work instruction, who to install, how to do, how to monitor, and so on. Should the procedure exist, the error is preventable, if happens, the one who is responsible will be discovered sooner or later.

The legal case study from the above incident from the staff’s side who took and install the CO₂ tube is to be applied chapter 359 KUHP (Criminal Code) stated that: Whoever due to his/her error (negligence) causing loss of one’s life, will be sentenced 5 (five) years the latest or one year in jail. Meaning of negligence is careless, even in Criminal Code (KUHP), negligence could mean to err or careless. R Soesilo explains negligence according to chapter 359 Criminal Code (KUHP) said “because of the mistake” equals to careless, forget, does not care.

The expert of criminal law said differently, negligence, careless was called culpa. Wirjono Prodjodikoro said the meaning of culpa was “mistake in general”, yet in law it has technical meaning, namely a crimed committed by a criminal which is not as much as intentional, that is careless so that an intentional cause occurs.

Jan Remmelink said the bottom line was culpa included inaccurate thinking, lack of knowledge or act less accordingly, culpa here refers to mental ability of someone and therefore it could be said that culpa menans no or less suspect in real (probably occurs) due to fatal action of someone – whereas it is easy to be done and it should be done.

No tolerance given for the mistake of the paramedics taking CO₂ tube instead of N₂O as doctor ordered, the inaccurate action caused a result of a medical attempt aimed at operating a broken leg ended with death.

Literally, malpractice means bad practice. Black’s Law Dictionary defines malpractice as “unprofessional misconduct or unreasonable lack of skill. If paying attention to the above understanding, clearly malpractise is not a monopoly of medical profession (doctor). It also applies to legal profession (advocate, judge) or banking (accountant). When associated with medical profession then it is mentioned as medical malpractice. The term malpractice was first used by Sir William Blackstone in 1768, stating malapraxis is great misdemeanor and offence at common law, whether it be for curiosity or experiment or by neglect: because it breaks the trust which the party had place in his physician and tend to the patient’s destruction. Meanwhile, according to M. Yusuf Hanafiah, medical malpractice is negligence of a doctor to use his ability level and common knowledge carried out to cure patient or wounded person according to the measure in the same environment.

World Medical Association shows that medical malpractice could happen because of intentional action (intentional) such as certain misconduct, negligence or inexcusable incompetence. Medical malpractice view can be associated with unauthorized factor or without competence is understandable if negligence in the medical field is not intentional since doctor never intends to kill the patient that is being cared. Doctor will do whatever it takes (inspanning verbintenis) to make the patient getting better, therefore medical negligence is not a crime but negligence, when the switch of medical gas tube was intentional (intent/opzet), the paramedic must be charged. If the error is negligence (negligence/culpa), then it could be granted with compensation. However, if the negligence caused material loss, accident even taking one’s life, it could be classified as serious negligence (culpa lata) and criminal. Meanwhile the condition to determine medical malpractice with criminal is due terms, which caused a loss for health namely wound (chapter 90 – Criminal Code/KUHP) or loss of one’s life so that it could be the element of crime.

Negligence or careless, does not care towards other’s needs or not doing what others do carefully. In the medical law dictionary, patient’s risk and negligence can be differentiated, where doctors could be held accountable, the risk that patient bears such as: accident (accident, mishap, and misadventure), risk of treatment, and error of judgement. So that the medical law problem 80% will be on judging and interpreting, if there is negligence, doctor can be held accountable, however should there be a risk of medical measures, the patient must accept it.

Malpractice in other words wrongdoing or neglect of duty, this understanding applied if a doctor commits a wrong medical procedure (wrong doing) or he/she does not care enough to treat a patient (neglect the patient by giving not or not enough care to the patient). According to Oxford Dictionary: malpractice is wrongdoing (law) improper treatment of patient by medical attendant, illegal action for one’sown benefit while in position of trust, It can be said that wrongdoing will occur if there is a intentional element (opzet) and illegal practice element which means it is an illegal action or against the law, as well as unethical practice.

The author suggests that nowadays the medical service could be included in the draft of Criminal Code, where the
element of Regulation of the Minister of Health no. 2052 chapter 21 and 22 explains that the protection for consumers including commercial service provider and professional service provider where the regulation on rights and obligations is different between the businessman and the service provider. Service provider provides its service according to the serving standard, profession standard and standard operating procedure; therefore paramedics could not be charged or in other words, be given immunity right.

IV. CONCLUSION

The use of medical gas in the healthcare facilities becomes specific since the medical gas consists of pure medical gas and mixed medical gas, each has different purpose. Pure medical gas namely Oxygen, Dinitrogen Oxide (N$_2$O), Nitrogen, Carbon dioxide (CO$_2$), Helium, Argon, medical compressed air and instrument air. While mixed medical gas is mixture of pure medical gas.

The use of the medical gas and medical vacuum in the healthcare facility is carried out through medical gas installation system, medical gas tube, portable oxygen concentrator and/or portable medical vacuum device. Medical gas and medical vacuum are used at operating room, intensive room or emergency room.

The use of medical gas, every hospital must make a special installation, where the setting can be monitored through one integrated system between user’s room and the medical gas source. Standard Operating Procedure must be followed, especially the use of medical gas in operating room in different design by using special tubing, for example when tubing suddenly loose, then the staff in charge will soon find out. Medical gas requirements and its equipment referred to Regulation of Minister of Health number 1439/2002.

Regulations and SOP available are include in the hospital basic regulation PDRS (basic hospital rules) or PD Medical (Hospital by Laws and Medical by Laws) can be used for consideration if there is alleged error in a medical case.

V. SUGGESTION

To prevent error or negligence by the paramedic, there must be a training on how to use the medical gas for all paramedics before their assignment in a hospital and it is necessary for stakeholders to pay attention to the rules as stated on the Regulation of Minister of Health number 04/2016 and Decree of Minister of Health number 1439/2002. The bottom line is to prioritize the consumers’ needs where the installment of the medical gas in the healthcare facilities must meet security, design, location, storage, and other supporting equipment requirements. The installation of medical pipe and the number of medical gas outlet installed must be as required and equipped by faucets, pressures, gauge, alarm, and other warning specification alarm.

The hospital installed the medical gas centralized through channel pipe divided into 2 (two) types: O$_2$ (Oxygen) and N$_2$O (Nitrogen) for patients in need through hose or regulator available in the hospital.

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