

Analysis of Patient Safety in TM/CAM Services, Women's Health and its Legal Perspective

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ABSTRACT

Ensuring patient safety is a crucial aspect of healthcare including TM/CAM, particularly in the field of women's health. Healthcare providers must prioritize the safety of women during pregnancy and childbirth to prevent any harm or potential risks. This research used a traditional review, increasing the amount of literature that has been read and analyzed by the researcher. Normative-juridical principles in a prescriptive analytical manner with a statutory regulatory approach and the thinking method is deductive. General patient safety principles can be used in TM/CAM services by implementing the International Classification of Patient Safety (ICPS). Women are at risk due to their genital, hormonal, and pregnancy characteristics and may be affected by disease conditions acquired before or during pregnancy, and complications from physiological events at the end of pregnancy. Regulations on traditional health services and women's health care in Law No. 17 of 2023 and other regulations. This arrangement must guarantee safety, quality, and affordability. Patient safety is specifically regulated by Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017 concerning Patient Safety. TM/CAM health services have developed in society and have to assess quality and safety standards, registration and accreditation have been established and TM/CAM health service practitioners, both those with formal and non-formal education, are required to have a competency certificate and Registration Certificate (STR). And Licenses (SIP) and Traditional Healers Registered Certificate (STPT).

Keywords: TM/CAM, Patients Safety, Women's Health and Legal perspective

INTRODUCTION

Patient safety in women's health is an essential priority within the healthcare industry. As healthcare providers continue to evolve and improve the standard of care, it is vital to recognize and address the specific needs and challenges unique to women's health.

Ensuring patient safety is a crucial aspect of healthcare, particularly in the field of women's health. Healthcare providers must prioritize the safety of women during pregnancy and childbirth to prevent any harm or potential risks.

Implementing protocols and guidelines specifically designed for women's health can significantly reduce medical errors and improve patient outcomes Thus, it is important to have prenatal care visits to verify the normal course of pregnancy and ensure early detection of potential pathological conditions that may affect the health of the pregnant woman or the outcome of her pregnancy.

For example, a pregnant woman or her fetus may be affected by disease conditions acquired before or during pregnancy, such as congenital syphilis, by situations inherent to the pregnancy itself such as preeclampsia, or by complications from physiological events. late in pregnancy, such as postpartum hemorrhage. All of these conditions require timely recognition by a doctor so that the risk can be reduced to a minimum acceptable level for both mother and fetus. In the case of congenital syphilis, the acceptable risk should not be greater than 5 x 10,000, to eliminate congenital syphilis for pregnant women with preeclampsia, the risk of death from eclampsia should not be more than 2%; and regarding postpartum hemorrhage, the risk of extreme maternal morbidity, and the risk of death from these causes, should not be greater than 2.5% and 2%, respectively (Chen, 2019), (Garovic et al., 2022), (Fang et al., 2022), John R Smith; 2022, World Health Organization; 2023, (Günaydın, 2022),

Several studies have found that near misses are 3 per 1000 live births and mortality from postpartum hemorrhage (PPH) is 6.6% (range 0.0%-40.7%). The mortality index was highest in low-income countries and lower-middle-income countries. Overall, PPH was the most frequent contributor to obstetric hemorrhage, with atonic uterus identified as the main cause. (Maswime & Buchmann, 2017).

The figures considered to be the minimum risk currently come from high-income countries and may be considered the best achievement so far. How to explain that the risk of poor health outcomes is higher in low- and middle-income countries? Health determinant factors are a collection of individual, social, economic, and environmental domain factors that influence the health of an individual or a population.

Implementing protocols and guidelines specifically designed for women's health can significantly reduce medical errors and improve patient outcomes. In addition to specific protocols and guidelines, healthcare facilities should also focus on providing comprehensive education and training to their staff regarding the unique healthcare needs of women. This includes understanding the physiological and psychological aspects of women's health, as well as addressing disparities and biases that may impact the quality of care provided. Moreover, promoting open communication and creating a supportive environment for patients to voice their concerns is instrumental in ensuring patient safety in women's health.

In 2018, WHO reported that there were 134 million adverse safety incidents each year, resulting in 2.6 million deaths in underdeveloped and developing countries. In contrast to prosperous countries, this happens It is estimated that only about 1 in 10 patients experience a feeling of safety in a hospital. There were 7465 patient safety incidents in Indonesia based on reports from the National Patient Safety Commission (KNKP) in 2019. This number has increased significantly from 2018, which was 1489 incidents. From 7465 events, there were 38% near-injury events (KNC), 31% non-injury events (KTC), and 31% unexpected events. Based on the severity of the injury, there were 80 patients (1.7%) who were seriously injured and 171 (2.3%) died in 2019. So it can be concluded that special attention is needed to patient

safety in Indonesia. So hospitals must carry out accreditation every 3 years as hospital quality control. Hospital accreditation aims to maintain and improve the quality of hospital management, the quality of hospital services, and health safety services to patients. By assessing hospital accreditation and maintaining compliance with hospitals against quality and safety management standards for the improvement of sustainable hospital quality. Hospital accreditation must be carried out based on applicable standards.

According to the Institute of Medicine, patient safety involves preventing harm resulting from errors in action or inaction. On the other hand, organizational safety culture results from the values, attitudes, perceptions, skills, and behavior of individuals and groups. This culture determines the organization's health and safety management commitment, style, and skills.

Healthcare systems must create environments that reduce unintentional injuries to ensure patient safety. These actions are carried out through operational processes and procedures that minimize possible errors and make it easier to catch them before they occur. Safety culture is employees' long-term assumptions, values, beliefs, and actions about how open an organization is to spotting mistakes and learning from them. Safe care has a positive impact on mortality, illness, the length of a person's stay in the hospital, and costs. Patient safety depends largely on how healthcare providers feel about their work. Those with more positive attitudes tend to have higher levels of patient safety.

This healthcare system includes intangible features that are influenced by professional leadership, supervision, and feedback. Healthcare providers recognize their important role in regularly monitoring procedures and implementing best practices for continuous improvement.

Several challenges hinder the establishment of a safety culture, such as lack of creativity, poor professional and moral competence, limitations in judgment and clinical decision-making, inadequate knowledge and abilities in care management, and lack of willingness to improve professional competence. Conversely, inexperienced nurses can endanger patient health due to overconfidence, resistance to change, and outdated competencies.

Lack of communication during handover when changing nursing duties is the main reason for hospital disasters or sentinel events. As an important safety and quality issue, regulators and healthcare providers actively address communications at the time of handover changing nursing duties.

The World Health Organization (WHO), as a world organization, in 2009 released data that 30-50% of the Chinese population still uses traditional services and medicines or Complementary Alternative Medicine (TM/CAM) to treat their illnesses and support them to be healthy. In the regions of Ghana, Zambia, Nigeria, and Mali, 60% of the population uses traditional health services and treatment. Then in Europe, North America, and surrounding areas, 50% of the population, with its large population, still uses traditional health services and treatments. Likewise, in the San Francisco and London areas, 75% of the population uses traditional health services and treatments. Not to mention other regions around the world. This shows that the fact that the population uses traditional health services and treatment is important for human life and has the potential for progress in its development.

Traditional/complementary and alternative health medicine (TM/CAM) is a group of diverse medical and healthcare systems, practices, and products that are not generally considered part of conventional medicine. Although there is debate regarding the clinical effects of TM/CAM interventions, surveys from various parts of the world consistently document that the majority of the population uses TM/CAM (Harris PE, et al; 2012, Katy L Coopera et al; 2013, Philip E Harrisa et al; 2014, (Lee et al., 2022) Thus, TM/CAM is a common

component in healthcare options globally and must meet patient demands for effectiveness and safety (Hernando Gaitan Duarte, (Gaitán-Duarte & Estrada-Orozco, 2021), Runciman w et al 2009 (Lestari et al., 2023)

The government needs to firmly formulate regulations regarding traditional health services and treatment, also women's health as well, the aim of which is for the government to provide legal certainty, and control the running of traditional health service and women's health businesses so that it will improve the quality of traditional health services and women's health for those who serve them. The importance of this arrangement is related to the principles of TM/CAM which are useful, safe, and effective. So that the use of TM/CM and women's health services can guarantee their rights and maintain patient safety.

Indonesian legal provisions regarding traditional health services and treatment are determined through Law No. 17 of 2023. Traditional health services and treatment businesses that run must follow the law and have greater compliance with every definite legal rule. Talking about this, the essence of the law is to meet the legal needs of service/business actors which not only regulates but also provides broad space and complete freedom to service/business actors in determining their needs. Thus, there is a legal relationship in the form of a contract between the doctor and the patient who uses TM/CAM and women's health services. So if a lawsuit occurs, the basis for the lawsuit is called malpractice.

RESEARCH METHODS

Literature reviews There are forms of systematic mapping study methods, systematic literature reviews, and traditional reviews. This research used a traditional review, which is a literature review often called a survey paper. With this traditional review method, the articles used as references become more specific, while not ruling out the possibility of various sources that are still relevant even though they have different discussion topics. In other words, the broader the researcher's insight, the more written works or literature the researcher has read and researched or analyzed. Patient safety for women's health and TM/CAM services using normative-juridical principles in a prescriptive analytical manner with a statutory regulatory approach and the sources are legal materials and the thinking method is deductive.

RESULTS AND DISCUSSION

Patient safety Traditional health (TM/CAM) services and Women's health.

In Indonesia the TM/CAM services, it is known as traditional health, in Law no. 17 of 2023 about Health is mentioned in Article 22 Article 1 point w states that traditional health services (TM/CAM) based on the method of treatment consist of a). Traditional health services that use skills; and/or b) Traditional health services that use herb Furthermore, TM/CAM Traditional Health Human Resources in (article 199) paragraph 1 point k. referred to as traditional health workers, hereinafter in paragraph 12, traditional health power consists of traditional health personnel, traditional healers, and traditional intercontinental health personnel. (TCM) The traditional health personnel category in article 199 paragraph 12 has formal education Diplome 3 herbal medicine and Bachelor of Applied Traditional Medicine which is internationally called Traditional Chinese Medicine (TCM).

Several other types of categories of traditional TM/CAM health workers as mentioned in WHO are still being developed and implemented through short/ long-term courses or training According to WHO, several groups have developed in the TM/CAM group: 1) Body

Mind Therapist group combining mental and breathing and body movements with for example meditation, biofeedback, hypnosis, yoga, tai chi, guided imagery, art therapy and so on 2) Practice-based group biological including vitamins, supplements, plants or herbs 3) manipulative groups including massage, chiropractic, reflexology 4) Use of energy such as reiki, touch healing, 5) Holistic approaches include Ayurvedic medicine: and Traditional Chinese Medicine including acupuncture naturopathic medicine, homeopathy, and the alexander technique In general, TM/CAM has been evaluated and proven to be safe and useful, but there are some whose safety is still unclear, but the benefits have been felt by the public subjectively. Some supplements or nutritional, herbal products circulating in the community have not received approval from the Food and Drug Administration (FDA) https://www.nhs.uk/conditions/complementary-and-alternative-medicine The World Alliance for Patient Safety has taken the initiative to reach a consensus on the International Classification of Patient Safety (ICPS) together with the WHO. ICPS is fundamentally clear in the collection, classification, and analysis of safety data. One important change is the renaming of 'adverse event' to 'harmful incident', which is intended to avoid the common confusion between the terms 'adverse event' and 'adverse reaction'.

The ICPS presents a classification of 13 types of incidents (WHO; 2009), such as 'clinical administration', 'clinical process', and 'clinical process'. behavior', which aims to be universally applicable. All incident types except one (oxygen/gas/vapor) could be potentially relevant to TM/CAM.

Patient safety principles can generally be used in TM/CAM services because ICPS has provided a conceptual framework and accompanying taxonomy that provides a method for organizing patient safety data for aggregation, analysis, and translation into usable information, as well as patient safety research guidelines. ICPS has been widely applied in various skills and specialties around the world but has not been widely reported for TM/CAM services.

Referring to the use of ICPS requires expertise in the field of TM/CAM to apply it more carefully. The competencies of TCM Doctors can be observed in the Entry-Level Occupational Competencies, Performance Indicators, and Assessment Blueprint for the Doctor of Traditional Chinese Medicine developed by the College of Traditional Chinese Medicine which consists of 12 competency areas. In Indonesia, there are 8 competency areas contained in the Intercontinental TM/CAM Professional Standards.

Competency areas regarding pass safety include the following

1. Evaluate the patient's risk profile.

- a Determine the risk profile relative to acupuncture treatment.
- b Determine the level of risk relative to TCM herbal remedies.

2. Provide a safe work environment.

- a. Maintains current knowledge of infectious diseases and infection control techniques.
- b. Implement universal precautions for infection control.
- c. Ensure effective supervision of staff and/or students.
- d. Inspect facilities for electrical hazards, fire risks, and physical hazards that could cause accidents, and take action to minimize them.
- e. Establish procedures and routes for emergency evacuation facilities.
- f. Establish procedures to maximize personal, staff, and patient protection in the event of abusive or violent behavior

3. Manage risks to patients.

a Include safety precautions in the herbal treatment plan.

- b Manage adverse reactions and accidents resulting from treatment.
- c Respond appropriately to medical emergencies.
- d Manage blood-to-blood contact and provide direction for post-exposure follow-up.
- e Clean up spilled blood and other body fluids.
- f Control and extinguish small fires.
- 4. Ensure equipment is safe and functional.
- a. Select equipment that improves patient safety.
- b Maintain equipment in good condition.
- c Clean equipment regularly, and disinfect as necessary

(Dr David Cane; 2014)

Patient safety for women is in principle the same as the principles and concept of patient safety in general, but several things need to be considered as a vulnerable risk group as follows Women with feminine health are at risk due to the genital, hormonal, and developmental nature of pregnancy and may be affected by disease conditions acquired before or during pregnancy, such as congenital syphilis, by conditions inherent to the pregnancy itself such as preeclampsia, or by complications from physiological events. late in pregnancy, such as postpartum hemorrhage.

Therefore, the first step in safe healthcare delivery is to identify and study the patterns and causes of errors in the delivery system and to adopt and develop safe practices that reduce the likelihood of system failures that can lead to adverse outcomes. A fair patient safety culture also recognizes the responsibility of all healthcare providers to follow safe practices and to avoid behavior that could be categorized as "risky behavior" or "reckless behavior." Risky or reckless behavior must become a policy and system for all organizations and leaders that allow promoting and increasing error reporting and identifying potential hidden problems, as well as motivating health service providers and collaborating to overcome system failures. One of them is optimizing communication and collaboration between various members of the health service team, which is equally important in promoting patient safety principles.

Furthermore, the technical importance of implementing recommended safe treatment practices, namely problems related to drug use; including the use of herbs in TC/CAM, therefore, an effort to reduce the occurrence of errors. Even though there is a computerized system, there may be errors in prescribing and administering medicines/herbs\By improving handwriting legibility, Avoid using non-standard abbreviations, Check for allergies and drug sensitivities Always use a leading 0 for doses less than 1 unit (e.g., 0.1 mg, and never use an additional 0 after the decimal (e.g., 1 mg, not 1.0 mg):

All verbal orders must be written down by the individual receiving the order and read back to the prescriber verbatim Reduces the possibility of surgical errors Surgical errors may involve the performance wrong operation or procedure in the wrong location or wrong patient. Although these errors occur much less frequently than medication errors, their consequences these errors are always significant. To address this surgical issue, The Joint Commission developed "Speak Up" designed to ensure the correct person, correct location, and correct procedure through pre-procedural verification elements. process, marking the procedure location, and taking a "time-out" before starting the procedure.

The World Health Organization's Safe Surgery Lifesaving Program, supported by the International Federation of Gynecology and Obstetrics (FIGO), has recently been shown to significantly reduce surgical morbidity and mortality in various settings.

The time that has the greatest potential for miscommunication is during patient handover. This occurs during shift changes for nurses, workers, or practice partners.

The information communicated during a handoff must be accurate to meet patient safety (Haynes AB et al; 2009, American College of Obstetricians and Gynecologists 2009, Committee on Patient Safety and Quality Improvement; 2015)

Legal perspective on patient safety, women's health, and TM/CAM

Traditional health services based on the method of treatment consist of a. Traditional health services that use skills; and/or b. Traditional health services that use knowledge are regulated in Law no. 17 of 2023 article 22 paragraph 1 point w. Health Personnel who provide TM/CAM Traditional Health services are regulated in (article 199) paragraph 1 point k. which consists of referred to as traditional herbal health personnel, traditional healer health personnel, and traditional intercontinental health personnel (TCM) as stated in Article 199 paragraph 12. The traditional health category in article 199 paragraph 12 has formal education Diploma 3 herbal medicine and Bachelor of Applied Traditional Healer Medicine and Bachelor of Applied Traditional Intercontinental Medicine which is internationally called Traditional Chinese Medicine (TCM).

Health efforts related to maternal, infant, and child health efforts, and traditional health are regulated in article 22 paragraph 1 points a and w Maternal health is an effort aimed at giving birth to healthy, intelligent, and quality children and reducing maternal mortality rates. As regulated in Article 40 paragraph 1 and paragraph 2 it is stated that the coverage includes the pre-pregnancy period, pregnancy, childbirth, and postpartum. Furthermore, in paragraph 3 it must be safe, high quality, and affordable Traditional health services are regulated in Article 160 (1). Traditional health services based on the method of treatment consist of a. Traditional health services that use skills; and/or b. Traditional health services that use herb / biological plans. It is stated that these services must be based on knowledge, skills, and/or values that are sourced from local wisdom. Traditional health services must be able to account for their benefits and safety and not conflict with socio-cultural norms.

Traditional health services can be provided in independent practices, community health centers, traditional health service facilities, hospitals, and other health service facilities. To improve the quality of each health service facility internally, it must carry out a. measuring and reporting quality indicators; b. Patient safety incident reporting; and c. risk management and externally must be carried out a. registration; b. license; and c. accreditation. With an orientation towards fulfilling quality standards, and fostering and improving service quality, the process is fast, open, and accountable. This arrangement is as stated in Article 178 paragraphs 1 to 4 The traditional health category in Article 199 paragraph 12 has formal education. Apart from that, in the community there are TM/CAM services provided by human resources which are carried out with short-term courses or training that follow the developments mentioned in WHO, including 1) Body Mind Therapist Group combining mental and breathing and body movements with for example meditation, biofeedback, hypnosis, yoga, tai chi, guided imagery, art therapy and so on 2) biologically based practice groups including vitamins, supplements, plants or herbs 3) manipulative groups including massage, chiropractic, reflexology massage lymphatic massage, etc. 4) Use of energy such as reiki, touch healing, 5) Holistic approaches include Ayurvedic medicine: naturopathic medicine: homeopathy and Alexander technique. But a special holistic approach is Traditional Chinese medicine including acupuncture already formal education The regulations in article 274 state that it is important for TM/CAM health personnel to carry out services following professional standards, professional service standards, standard operational procedures, and professional

ethics as well as patient health needs; by 1) obtaining consent from the patient or his family for the action to be given 2) maintaining the confidentiality of the patient's health 3). make and keep records and/or documents regarding examinations, care, and actions taken; From the perspective of patients, they have the rights regulated in article 276 where patients have the right to a) obtain information about their health; b) receive an adequate explanation regarding the Health Services they receive c) receive Health Services following medical needs, professional standards and quality services; d) refuse or agree to medical treatment, except for medical action necessary for the prevention and control of infectious diseases Outbreak or pandemic; e) gain access to information contained in medical records; f). ask for the opinion of Medical Personnel or other Health Personnel; and g). obtain other rights following the provisions of statutory regulations

This patent right is also related to Law of the Republic of Indonesia Number 8 of 1999 concerning Consumer Protection where as a patent consumer has the rights stated in article 4, namely a. the right to comfort, security and safety in consuming goods and/or services; b. the right to choose goods and/or services and obtain said goods and/or services in accordance with the exchange rate and conditions and guarantees promised; c. the right to correct, clear and honest information regarding the conditions and guarantees of goods and/or services; d. the right to have opinions and complaints heard regarding the goods and/or services used; e. the right to obtain appropriate advocacy, protection and efforts to resolve consumer protection disputes; f. the right to receive consumer guidance and education; g. the right to be treated or served correctly and honestly and not in a discriminatory manner; h. the right to receive compensation, compensation and/or replacement, if the goods and/or services received are not in accordance with the agreement or are not as they should be; i. rights regulated in other statutory provisions.

Law no. 17 of 2023 does not yet have implementing regulations such as government regulations, however, based on article 453, it is stated that all statutory regulations that are implementing regulations of previous or other similar laws are declared invalid after Law no. 17 of 2023 concerning health is declared to remain valid as long as it does not conflict with the provisions of this Law.

Based on Article 453, several regulations regarding traditional health can still be used as material for traditional literature reviews using normative-juridical principles in a prescriptive analytical manner with a statutory regulatory approach. with a deductive method of thinking

Regulations for the implementation of traditional medicine are regulated in Government Regulation (Peraturan pemerintah =PP) No. 103 of 2014 concerning Traditional Health Services (TM/CAM). There are 3 types of traditional health services, namely:

Empirical Traditional Health Services are the application of traditional health whose benefits and safety are empirically proven.

Complementary Traditional Health Services are the application of traditional health that utilizes biomedical and biocultural science in its explanations and its benefits and safety are scientifically proven.

Integrated Traditional Health Services is a form of health service that combines conventional health services with Complementary Traditional Health Services, either as a complement or a substitute.

The current services in hospitals, and health centers have provided integrated traditional health services which include several aspects such as: A holistic approach by examining the patient's physical, mental, spiritual, social, and cultural dimensions.

Prioritize effective relationships and communication between health workers and patients; Given rationally; Held with the patient's informed consent (Informed Consent); Prioritize a natural approach; Improve self-healing ability;

In the Regulation of the Minister of Health of the Republic of Indonesia no. 15 of 2018 concerning complementary traditional health services, where article (1.1) stated that Traditional Health Services are treatment and/or care using methods and medicines that refer to experience and skills passed down empirically which can be accounted for and applied following the norms applicable in community, and article (2.2) Complementary Traditional Health Services is the application of traditional health that utilizes biomedical and biocultural science in its explanation and its benefits and safety are scientifically proven. Then, in article (3.1.2) Complementary Traditional Health Services are carried out by Traditional Health Personnel in traditional health service facilities. Apart from being carried out in traditional health service facilities, Complementary Traditional Health Services as intended in paragraph (1) can be carried out by Traditional Health Personnel in other health service facilities in the form of integrated Traditional Health Services following the provisions of statutory regulations. And traditional health services have distinctive characteristics as stated in article (5.1). Complementary traditional health services have distinctive characteristics such as traditional, culture-based health service concepts, procedures for determining individual health conditions (diagnosis procedures), determining individual health conditions (diagnosis), and care/treatment management.

Regulations for traditional health personnel are regulated in several sub-sections, which are based on the skills and knowledge of traditional health personnel, both knowledge about the disease, how to treat disease, and how to make traditional medicine concoctions carried out by traditional health personnel, namely as follows.

Regulations for traditional health personnel healers are contained in the Republic of Indonesia Minister of Health Regulation No. 15 of 2018 concerning complementary traditional health services, in the article (1.3) it is stated that Traditional Health Personnel are every person who dedicates themselves to the traditional health sector and has knowledge and/or skills through education in the traditional health sector which for certain types requires an authority to carry out traditional health services, which are proven by STRTKT, furthermore, in article (1.9), namely, the Traditional Health Personnel Registration Certificate, hereinafter abbreviated to STRTKT, is written proof of the granting of authority to provide Complementary Traditional Health Services. As well as the letter of the license in article (1.10), namely, the License to Practice for Traditional Health Personnel, hereinafter abbreviated as SIPTKT, is written evidence given to Traditional Health Personnel in providing Complementary Traditional Health Services. In article (3.1.2) Complementary Traditional Health Services are provided by Traditional Health Personnel in traditional health service facilities. Apart from being carried out in traditional health service facilities, Complementary Traditional Health Services as intended in paragraph (1) can be carried out by Traditional Health personnel in other health service facilities in the form of integrated Traditional Health Services following the provisions of statutory regulations. In the third part of traditional health personnel: article (8.2) educational qualifications, Traditional Health Personnel consists of: Professional Traditional Health Personnel and Vocational Traditional Health Personnel Article (8.3), professional Traditional Health Workers as referred to in paragraph (1) letter a are Traditional Health Personnel who have graduated from higher education in the field of traditional health at least from a professional education program following the provisions of statutory regulations. Article (8.4), Vocational Traditional Health Workers as referred to in paragraph

(1) point b are Traditional Health Personnel who have graduated from higher education in at least three diploma programs in traditional health fields following the provisions of statutory regulations. Article (9.1) Traditional Health Personnel in providing traditional health services:

Sorting and evaluating clients' conditions in complementary traditional health services that can be carried out by traditional health personnel or other traditional health problems that must be referred; Only use traditional medicines that have a distribution permit or self-concocted traditional medicines, and do not administer and/or use medicinal chemicals, including over-the-counter medicines, limited over-the-counter medicines, hard drugs, narcotics and psychotropics, and dangerous substances; Do not take action using radiation;

Do not carry out invasive procedures and use medical devices unless by their competence and authority; and Do not sell and/or distribute self-contained traditional medicines without permission following statutory provisions.

In the article (9.2), in sorting and evaluating clients' conditions as referred to in paragraph (1) letter a Traditional Health Personnel can use certain medical diagnostic support tools following methods, competence, and authority. Furthermore, in articles (10.1 and 2) it is explained that Traditional Health Personnel of foreign nationalities can be utilized in Complementary Traditional Health Services in the context of transferring science and technology. The utilization of Traditional Health Workers of foreign nationals as referred to in paragraph (1) is carried out at the request of traditional health education institutions and Griya Sehat (health homes) which are used as educational vehicles following the provisions of statutory regulations.

The government issued supporting regulations such as regarding Traditional Health Services, Minister of Health Regulation no. 90 of 2013 concerning SP3T, Minister of Health Regulation no. 8 of 2014 concerning SPA, Minister of Health Regulation no. 9 of 2016 concerning Efforts to Develop Traditional Health Through Independent Care Using TOGA and Skills, Minister of Health Regulation No. 61 of 2016 concerning Empirical Traditional Health Services, Minister of Health Regulation no. 37 of 2017 concerning Integrated Traditional Health Services, Minister of Health Regulation no. 15 of 2018 concerning Complementary Traditional Health Services, Minister of Health Regulation no. 34 of 2018 concerning Licensing and Implementation of Therapist Acupuncture Practices.

The challenges of implementing traditional medicine in Indonesia can be seen from data from the Ministry of Health in 2011 which determined that herbal medicine or herbal medicine was included in primary health services and made it a flagship or superior program. Although herbal medicines in Indonesia have been known for a long time, most of them do not have a scientific background to confirm their efficacy. This becomes an obstacle when entering the formal world. The reason is, in the world of modern medicine (conventional medicine) we currently adhere strongly to Evidence-Based Medicine (EBM) in every medical decision we make.

Regulations on the use of traditional medicines and their services in Indonesia are currently quite good, but regarding the development of the use of medicinal plants as treatment, there needs to be research, a review of scientific literature, and the development of further research that supports the use and efficacy of herbal medicines and traditional medicine method If you look at the differences between complementary traditional medicine and conventional medicine, this sometimes gives rise to debate regarding the effectiveness of using traditional medicine without any side effects compared to conventional treatment, even though in reality this is not always the case. This could be because traditional medicine has a more holistic (comprehensive) approach, while conventional treatment has a

symptomatic approach (focusing therapy on the symptoms that arise). In general, the regulations and services for traditional medicine in Indonesia are clear, because they have been regulated in legislation as well as Governor Regulations for provincial areas.

To improve the quality of traditional health services (TM/CAM) there have also been regulations starting with registration, accreditation, and licensing for health service facilities and every health personnel who practices is required to have STR and SIP

Specifically for patient safety, it is also regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 11 of 2017 concerning Patient Safety where Article 2 states that the Patient Safety Regulation aims to improve the quality of health service facilities through the implementation of risk management in all aspects of the services provided by the facility. health services.

A National Patient Safety Committee has also been formed, which in Article 2 carries out its functions preparation of Patient Safety standards and guidelines; preparation and implementation of Patient Safety programs; development and management of Incident reporting, analysis, and compilation systems Patient Safety recommendations; cooperation with various related institutions both domestic and foreign; And monitoring and evaluating the implementation of the Patient Safety program.

In particular, services for women's health / female patients in a regulatory manner with a multi-disciplinary approach have been formulated following Article 23 paragraph (2) and Article 26 paragraph (3) of Law Number 52 of 2009 concerning Population Development and Family Development, and Article 18, Article 25, and Article 28 of Government Regulation Number 61 of 2014 concerning Reproductive Health, needs to regulate health services for the pre-pregnancy period, pregnancy period, childbirth, post-natal period, contraceptive services and sexual health services; With the implementing regulations as stated in the Regulation of the Minister of Health of the Republic of Indonesia Number 21 of 2021 concerning the Implementation of Health Services for the Pre-Pregnancy Period, Pregnancy Period, Childbirth, and Post-Birth Period, Contraception Services, and Sexual Health Services wherein Article 2 Regulations for the implementation of Health Services for the Pre-Pregnancy, Pregnancy, Childbirth, and Post-Birth Period, Contraception Services, and Sexual Health Services aim to reduce the morbidity and mortality rates of mothers and newborns by a. preparing the health of teenagers, prospective brides, and/or couples of childbearing age before pregnancy; b. ensuring the health of mothers so that they can give birth to a healthy and quality generation; c. guarantee the achievement of quality of life and fulfillment of reproductive rights; d. guarantee the quality of Contraception Services, and maintain and improve the quality of maternal and newborn health services Traditional health service practices that do not have formal education and some are even carried out based on experience and skills can be categorized as traditional health services and treatments according to the law, but only those that meet the empirical test requirements and do not violate the norms that apply in society are those that can operate according to the provisions of the law.

In particular, the government has regulated the Regulation of the Minister of Health of the Republic of Indonesia Number 61 of 2016 concerning Empirical Traditional Health Services. Article 2 of this regulation aims to:

- a. realizing the provision of safe and beneficial Empirical Traditional Health Services;
- b. guidelines for the implementation of Empirical Traditional Health Services for the government, regional governments, and traditional healers; And

c. guidelines for implementing tiered guidance and supervision by the government and related sectors regarding the implementation of traditional health services.

Empires Traditional Health Services are carried out by Traditional Health healers based on knowledge and skills acquired from generation to generation through apprenticeships or non-formal education. Knowledge and skills obtained from non-formal education are obtained through training or courses as proven by a competency certificate issued by the Competency Certification Institute (Lembaga Sertifikasi Kompetensi) which is a partner and recognized by the Course and Training Development Directorate of the Ministry of Education and Culture following the provisions of statutory regulations as mentioned in article 3 paragraphs 1 to 5 Article 4 regulates that Traditional Healers who will provide Empirical Traditional Health Services are required to have a Traditional Healers Registration Certificate (STPT) which is only given to Traditional Healers who do not carry out interventions on the body that are invasive and do not conflict with the concept and characteristics of traditional empirical health services.

Thus, it is hoped that with this arrangement, the quality of traditional health services and treatment can be improved and will not cause side effects that cannot be medically justified. Achieve safety, useful, and felt useful by the community

CONCLUSION

With the increasing TM/CAM services in the community, especially women, attention is needed to regulate the existence of standards to achieve quality, registration, and accreditation of all health service facilities. Specifically regarding patient safety, a patient safety system has been developed with the formation of the National Patient Safety Committee. TM/CAM health service practitioners, both those with formal and non-formal education, are required to have competency certificates. With this competency certificate, they must have a Certificate of Registration (STR) and a Licence (SIP) for health personnel with formal education and a Traditional Healers Registered Certificate (STPT) for non-formal healers Considering that female patients are a vulnerable group, the government has made various regulations to ensure the safety of female patients.

REFERENCES

- American College of Obstetricians and Gynecologists. Code of professional ethics of the American College of Obstetricians and Gynecologists. Washington, DC: ACOG; 2008. Available at: http://www.acog.org/from_home/acogcode.pdf. Retrieved July 30, 2009.
- Angga Suryawinata, Sri Sundari, Qurrotul Aini; Analyzing an Implementation of Patient Safety Targets Standards at Ja'far Medika Hospital Based on Hospital Accreditation National Standards (SNARS) Issue 1.1 Jurnal Aisyah: Jurnal Ilmu Kesehatan, 7(S1), 2022, –288
- Berrin Günaydın (2022) Management of Postpartum Haemorrhage Turk J Anaesthesiol Reanim 2022;50(6):396-402 DOI:10.5152/TJAR.2022.21438
- Committee on Patient Safety and Quality Improvement (2015) Patient Safety in Obstetrics and Gynecology ACOG Committee Opinion No. 447 Reaffirmed 2015

- E Lyn Lee, Noni Richards, Jeff Harrison, Joanne Barnes (2022) Prevalence of Use of Traditional, Complementary and Alternative Medicine by the General Population: A Systematic Review of National Studies Published from 2010 to 2019 Drug Safety (2022) 45:713–735 doi.org/10.1007/s40264-022-01189- Published online: 5 July 2022
- Eni Puji Lestari, Mira Triharini, Nuzul Qur'aniati (2023); Patient Safety Culture Instrument: A Systematic Review Medical Technology and Public Health Journal Vol. 07 No. 2 (2023) DOI: 10.33086/mtphj.v7i2.4717 //journal2.unusa.ac.id/index.php/MTPHJ
- Garovic, V. D., Dechend, R., Easterling, T., Karumanchi, S. A., Baird, S. M. M., Magee, L. A., Rana, S., Vermunt, J. V., & August, P. (2022). Hypertension in Pregnancy: Diagnosis, Blood Pressure Goals, and Pharmacotherapy: A Scientific Statement From the American Heart Association. *Hypertension*, 79(2), E21-E41. doi.org/10.1161/HYP.000000000000000000
- Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, et al. A (2009) surgical safety checklist to reduce morbidity and mortality in a global population. Safe SurgerySaves Lives Study Group. N Engl J Med 2009;360:491–9.
- Hernando Gaitán-Duarte, Kelly Etrada-Orozco; Safety in healthcare services, a worldwide priority in women care; Revista Colombiana de Obstetricia y Ginecología Vol. 72 No. 2

 2021John R Smith (2022) Post partum Hemorrhage, Medscape April 2022,
- Juang Putra Telaumbanua, Rahmat Dachi, Janno Sinaga, .Wisnu Hidayat, Evawani Silitonga (2023) Factors influencing the implementation of patient safety culture in mitra sejati hospital, medan city in 2022 Science Midwifery, Vol 10, No. 6, February 2023 www.midwifery.iocspublisher.org
- Juliet Fang, Elizabeth Partridge, Geoanna M. Bautista, Deepika Sankaran (2022) Congenital Syphilis Epidemiology, Prevention, and Management in the United States: A 2022 Update Cureus 14(12): e33009. DOI 10.7759/cureus.33009
- Runciman W, Hibbert P, Thomson R, Van Der Schaaf T, Sherman H, Lewalle World Alliance for Patient Safety. The Conceptual Framework for the International Classification for Patient Safety. Geneva: World Health Organisation, 2009. Disponible en: https://www.who.int/patientsafety/taxonomy/icps_full_report.pdf
- Maswime Salome, Eckhart Buchmann (2017) A systematic review of maternal near miss and mortality due to postpartum hemorrhage(Int J Gynaecol Obstet 2017 Apr;137(1):1-7. doi: 10.1002/ijgo.12096. Epub 2017 Jan 24.
- World Health Organization (2023) A Roadmap to combat postpartum haemorrhage between 2023 and 2030 A Roadmap to combat postpartum haemorrhage between 2023 and 2030 Geneva: World Health Organization; 2023. Licence: CC BY-NC-SA 3.0 IGO
- WHO global report on traditional and complementary medicine 2019. Geneva: World Health Organization; 2019. Licence: CC BY-NC-SA 3.0 IGO
- https://www.nhs.uk/conditions/complementary-and-alternative-medicine
- Xiang-Sheng Chen (2019) Turning off the tap: sustaining elimination of congenital syphilis through the programme targeting high-risk groups <u>J Glob Health.</u> doi: 10.7189/jogh.09.020312 1 December 2019 Vol. 9 No. 2 020312

Peraturan Perundang-Undangan

- 1. Undang-Undang Republik Indonesia Nomor 8 Tahun 1999 Tentang Perlindungan Konsumen
- 2. Undang-Undang Republik Indonesia Nomor 17 Tahun 2023 Tentang Kesehatan
- 3. Peraturan Pemerintah Republik Indonesia Nomor 103 Tahun 2014 Tentang Pelayanan Kesehatan Tradisional
- 4. Peraturan Pemerintah Republik Indonesai Nomor 61 tahun 2014 tenatng keehatan Reproduksi
- 5. Permenkes No. 90 tahun 2013 tentang SP3T,
- 6. Permenkes No. 8 tahun 2014 tentang Spa,

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- 7. Permenkes No. 9 tahun 2016 tentang Upaya Pengembangan Kesehatan Tradisional Melalui Asuhan Mandiri Pemanfaatan TOGA dan keterampilan,
- 8. Permenkes No. 61 tahun 2016 tentang Pelayanan Kesehatan Tradisional Empiris,
- 9. Permenkes No. 37 tahun 2017 tentang Pelayanan Kesehatan Tradisional Integrasi,
- 10. Permenkes No. 15 tahun 2018 tentang Pelayanan Kesehatan Tradisional Komplementer,
- 11. Peraturan Menteri Kesehatan No. 34 tahun 2018 tentang Izin dan Penyelenggaraan Praktik Akupunktur Terapis
- 12. Peraturam Menteri Kesehatan Republik Indonesia Nomor 11 Tahun 2017 Tentang Keselamatan Pasien
- **13**. Peraturan Menteri Kesehatan Republik Indonesia Nomor 24 Tahun 2018 Tentang Izin Dan Penyelenggaraan Praktik Tenaga Kesehatan Tradisional Jamu
- 14. Peraturan Menteri Kesehatan Republik Indonesia Nomor 17 Tahun 2021Tentang Izin Dan Penyelenggaraan Praktik Tenaga Kesehatan Tradisional Interkontinental

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