

**THE APPLICATION OF PORCINE BASED MEDICINE IN PREGNANCY AND
PUERPERIUM AS PREVENTIVE MEDICINE FROM MAQASID SHARIAH:
A LITERATURE REVIEW**

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Abstract	<p><i>Physiological changes in pregnancy makes the pregnancy is in hypercoagulable state. The risk further increase as the pregnant women had other associated medical comorbidity. The problem statement of this paper has commenced when recent 2016/2017 statistic in Malaysia revealed that the principal cause of maternal death in pregnancy is Venous Thromboembolism (VTE) particularly Pulmonary Embolism (PE). Thus, it is crucial to prioritize on prevention (al-wiqayah) before it happens. The treatment of obstetrical VTE both prophylactic or treatment dose with anticoagulant agent of Low Molecular Weight Heparin (LMWH) in specific (Enoxaparin Sodium) which is porcine based medicine is the main issue to be highlighted today. The objectives of this research are to explore the legitimacy of Clexane as preventive medicine of VTE during pregnancy and puerperium which is being used in Malaysian government hospitals as permitted by Malaysia Ministry of Health (MOH). Secondly, to harmonize the decisions between authorities, including Malaysia National Fatwa Council (MNFC), JAKIM and MOH decision regarding the prohibition of Clexane usage among Muslims. This qualitative research of methodology is utilizing interview and document review analysis. The finding of this research is the new dimension of fatwa is proposed for practicality in Malaysian hospitals which weighing al-hajah al-shariah can be a legal parameter in determining Islamic ruling. The need (al-hajah) to have preventive medicine eventhough it presents as porcine based medicine which declared by Islamic Jurisprudence could appear as a new contemporary ijthad in epistemic of fiqh al-waqi' in Malaysia nowadays. In fact, this decision will parallize the stance between JAKIM, MNFC and MOH regarding the practice that contrast with fatwa issued.</i></p> <p>Keywords: <i>Porcine, medicine, pregnancy, puerperium, maqasid.</i></p>
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INTRODUCTION

Islam prioritizes the well-being and health as wealth for human being. In fact, preservation of health (*hifzu al-nafs*) is one of the objectives of shariah (*maqasid al-shariah*) (Ibn 'Ashur, 2001). Therefore, Muslims are required to take care of their health and immediately encourage to search and choose halal medicines for the benefit of good health. According

to Nurdeng Deuraseh (2012), Muslims are required to be optimistic in preserving health as well as lives, in order to improve the quality of life (*hifz al-sihhah*) and should be added as a new essential value of maqasid al-shariah nowadays.

PROBLEM STATEMENT

Obstetrical VTE is recorded as the principal cause of maternal mortality in recent Malaysian statistic (Department of Statistic, 2017). Despite of significantly experienced improvements in safe motherhood in which from 540 per 100,000 live births in 1957 to 28 per 100,000 in 2010 (Yadav, 2014; Ravichandran & Ravindran, 2014 & Achanna et al., 2018), yet, the maternal death after 2008 seems to be plateaued (Majdah, 2017).

CVTE in particularly Pulmonary embolism seems to present with overlapping symptoms of pregnancy and might be missed, especially classical dyspnea and edema; it can be prevented with careful risk stratification and early treatment (Conti et al., 2014), by thromboprophylactic with LMWH as anticoagulant agent of choice. Studies has shown that LMWH had less complications compared to other LMWH agents of choices (I A Greer & Nelson-Piercy, 2005, Lussana et al., 2012, Ellison et al., 2000, Sirico et al., 2018).

Thus, achieving *maslahah* of safer motherhood, prevention and treatment of VTE by thromboprophylaxis during pregnancy and puerperium is required to be enhanced. Advocating on prevention in Islamic medical law (A R Gatrad, 2011) is very crucial especially to prescribe anticoagulant with LMWH (Clexane) in preventing and treating VTE mothers either high risk or intermediate risk categories.

High risk mothers with associated risk and complications to develop VTE is already indicated for this treatment without any hussle. Thromboprophylaxis treatment with Clexane as high-risk mothers are grouped under necessity (*darurah*) condition whom would be measured as *ghalabah al-dzan* (75%-99%) which means if not treated they may to end up with death.

The issue raise with the intermediate group of mothers', their cases are categorized in *zann 'adi* level whom measured as 51%-74% risk of approaching death. In fact, some intermediate risks patients can be considered as *hajah* condition, can be recalculated their risk and finally categorized into *darurah* as the risk changes and their condition upgraded into high risk such as caesarian mothers in puerperium (Royal College Obstetricians and Gynaecologists, 2015).

In another hand, some cases of intermediate risk mothers prior VTE, without minimum of four VTE/PE criteria's, might not require thromboprophylaxis by LWMH though their conditions are halve-life facing to death. This matter complicates as the VTE intermediate risk group of mothers whom not categorized as high risk (*darurah*) level but still receive prophylactic LMWH as preventive medicine, further question raised regarding that practice parallized or not to the fatwa issued by MNFC?

Practically, health physicians and obstetricians in Malaysia are permitted by MOH to use Enoxaparin Sodium (Clexane) as thromboprophylaxis in intermediate level of risk of VTE, including the high risk level too as stated in Clinical Practice Guidelines Prevention and Treatment of Venous Thromboembolism (CPG) published by MOH (Abdul Rashid & Jameela, 2013).

Indeed, preventive medicine theoretically using three components such *wasatiyyah*, *mizan*, *'adl* (Kasule, 2011) to promotes balanced health and clinically using thromboprophylaxis with Enoxaparin Sodium subsequently able to reduce the maternal mortality caused by VTE could be considered as *al-hajah* becoming the necessity (*Al-hajah tunazzal manzilat al-darurah*) (Mishkah, 2013).

As such, the crucial and important question raised is that to which extent *al-hajah al-shar'iyah* could be a principle in measuring the parameter level of fatwa in this particular case study in allowing the usage of Clexane at intermediate risk level as prevention will reduce the rate of acute intermediate risk of thromboembolism is considered as prophylaxis (Gao et al., 2015) not only in high risk (*darurah*) situation as above mentioned by MNFC.

In the sense of *fiqh al-waqi'* and *fiqh al-awlawiyyat*, maternal mortality related to embolism appeared crucial to be handled. Preventive medicine such as thromboprophylaxis by LMWH (Enoxaparin Sodium or Clexane) is highly recommended by evidences.

However, the issued fatwa on Clexane in 2009 explanation is just mentioned *darurah* situation without further elaboration about prophylactic by LMWH as preventive medicine to save mother's lives whom are dzan equivalent to 50% to fall into death, no only limited to *darurah* patients only.

In another hand; although the fatwa of Clexane issued in 2009 by MNFC which mentioned that Clexane is prohibited because it is made out of porcine intestinal mucosa, there were no further discussion despite it had undergone through the process of transformation (*istihalah*) MOH seemed had been opting the left-wing opinion, rather than obeying the MNFC's statement (Irwan, Nur Zaireena, Jameela, & Mohd Nasiruddin, 2018). Eventually, there is ambiguity forged in layman mind to which authorities their trust should underly since both JAKIM and MOH are playing vital role as Malaysian's trusted references.

MNFC claimed that, the halal alternative of LMWH, named Arixtra (Fondaparinux) is available thus it is the better option of treatment for Muslim patient. It was explained that it function is as equivalent to Clexane (JAKIM, 2015). However, recent data proved scientifically that LMWH (Clexane) is greater than UFH (Arixtra) in terms of efficacy and safety upon women and her baby (Sirico et al., 2018, Rowan et al., 2003; Lepercq, Conard, Borel-derlon, & Darmon, 2001) another point is that, Clexane being inexpensive compared to other drugs which should take into account on the economical impact (Weitz & Weitz, 2010).

Therefore, this research is embarked to propose a contemporary ijthihad of fatwa in concert to revisit the gazetted fatwa on clexane on 23-25 June 2009 without become *ifrat* or *tafrit*. Analyzing *qawa'id fiqhiyyah*, *qawa'id ululiyah*, *qawa'id maqasidiyyah* and some usul fiqh methodologies in justifying LMWH (enoxaparin sodium) or specifically Clexane as preventive medicine to reduce maternal mortality in Malaysia.

In the same time, the public will not be in the confusion state as authorities like NFC and JAKIM released the fatwa which not against to the practices of MOH today. Patient tend to follow the recommendation of treatment especially when it is supported by partner or organization or culture or religion or belief (Department of Health Queensland Government, 2013).

In fact, it is parallel to the *maqasid shariah* outline in particular to preserve lives as well as to alleviate the suffering of pregnant women as well as to achieve MDG goal as promoted by WHO which is to empower women's health whole wide world (United Nations, 2015).

METHODOLOGY

This research will employ qualitative data collection from primary data; interview with open-ended question and secondary data by reviewing documents, journals, previous theses, shariah's scholars books. All data collected will be examined critically through inductive and deductive method from 2008-2016.

RESEARCH FINDINGS

Venous Thromboembolism (VTE) Is A Culprit Of Maternal Mortality

The principal concern of the fifth of "Millenium Development Goal" (MDG 5) by World Health Organization (WHO) in 2015 which improving maternal health as among of global measure to achieve the status of developed country. Furthermore, VTE is the leading cause of maternal death in developed countries such as in Scotland (Kane et al., 2013), England (Sultan et al, 2013) and Australia (AIHW, 2017).

A safe motherhood campaign began in the year 1980 in Malaysia which aimed to alleviate mother's aggravation is the key of developed country other than modern hospitals and sophisticated hospital system regime.

Due to that critical statistic especially in Malaysia, study and analysis as well as efforts to reduce and to save human lives should be the attentions of contemporary shariah jurists. While Islam promotes the well-being of the nation (Al-SHatibi, 2010), the management and treatment of VTE to reduce maternal mortality is attributed as one of the important manner. Thus; this research extends on maqasid al-shariah view in preserving lives of mankind as well as maslahah and mafsadah in solving maternal death during pregnancy and puerperium. It is the key momentum that urges this research being initiated.

Pregnancy is when physiological process of women's body altered. Known that a normal pregnancy is associated with an hypercoagulable state characterized by increased concentrations of some pro-coagulant factors simultaneous decrease of other anti-coagulant factors such as protein C and protein (Vineeta, Prakash, & Renu, n.d). Although this is physiological condition, with added medical comorbidities leading to unstable condition, and finally women are facing VTE mortality and morbidity risk during pregnant and after delivery.

Even though the world witnesses the significant decline of maternal mortality in Malaysia from 1957-2010 (Yadav, 2014; A'isyah Sukaimi, 2018; Ravichandran & Ravindran, 2014; Hematram, 2006; Achanna, Krishnaswamy, Ponnampalam, & Bondhu, 2018) but Malaysia still need to intensify the safer motherhood as thromboembolism has become the leading cause of maternal mortality (Abdul Rashid & Jameela, 2013) since recent statistic on 2016 with regard maternal mortality shows its imbalanced situation when obtained data displays the major cause of maternal mortality is obstetric embolism followed by others (Abd Rahman et al, 2013 & Department of Statistic, 2017).

Thromboprophylaxis By LMWH Reduces The Rate Of Maternal Mortality

Many efforts has been done to reduce maternal morbidity and mortality, including training and providing the staffs with adequate knowledge about thromboembolism during pregnancy and puerperium, equipping on the knowledge on the drugs and methods that can be used to prevent thromboembolism so that it would be more efficient and systematic in dealing with thromboembolism (MOH, 2014).

As such, thrombolytic therapy for moderate risk women prior thromboembolism by prescribing (Clexane) with one dose per day according to the body weight (Medsafe, 2017) as prevention is sufficient as it could reduce maternal mortality statistic (Gao et al., 2015). Implying to this research, the thrombolytic therapy agent that could be recommended is Low Molecular Weight Heparin (LMWH) or Enoxaparin Sodium (Clexane) as prophylactic and anticoagulant therapy as its safety and efficacy proven in over 1000 pregnancies (Rowan et al 2003; Lussana et al, 2012 & Greer, 2015)

Statistic of PE death in 2010-2015 with ratio per 100,000 ethnic group indicated that Malay and Indian women with 3.64 and 2.63 respectively placed the highest ranking in contributing maternal mortality in Malaysia because of embolism (Majdah, 2017). Several variables have been forwarded as risks factors contribute to develop PE death such as trend of overweight and obesity, smoking habit, obstetric risk (F. H. D. D. MOH, 2018) including rejection on which suspicious of ingredient in Clexane which extracted from porcine intestinal mucosa (Irwan Mohd Subri et al., 2018).

Majdah, (2017) mentioned that VTE in specific PE death was proved by evidence that it is preventable as experimented on pregnant mother puerperium. The statistic regarding 89 cases in Malaysia showed a significant decline afterward thromboprophylaxis in postpartum period of time.

Due to that, the thromboprophylaxis during pregnancy and puerperium is a variable that need to be take note so that the system of it would be enhanced from all

respects including the modern interpretations of the Islamic Law as exemplified by the Malaysia National Fatwa Council (MNFC) as Islamic authority with along JAKIM.

Ministry of Health (MOH) stated in the training manual guideline of prevention and management of Thromboembolism during Pregnancy and Puerperium (MOH, 2018) that thromboprophylactic agents of choice of VTE has four types as following; First, Low Molecular Weight Heparin (LMWH), second, Unfractionated Heparin (UFH), Fondaparinux and fourth, Non-vitamin K Antagonist Oral Anti-Coagulants (NOACs).

Al-Hajah Al-Shar'iyah In Determining Islamic Ruling

Need (*Hajah*) had been described in the epistemic community of *maqasid shariah* (Al-Shatibi, 2010) in between two situations, *daruriyyah* and *tahsiniah*. *Hajah* can be defined literally as need to something (*al-iftiqar ila al-shay'*) (Al-Khadimi, 2002) while from technical definition, *hajah* consists several meanings according to Muslim jurists for instances, Al-Juwayni explained that *al-hajah* implies to the general need and it is not end up to the *daruriyyat* limitation of line (Al-Juwayni, 1399). Meanwhile, *maslahah* to which preserve the *maqasid shariah* is also known as *al-hajah* (Al-Asfahani, 1999).

In this research, Clexane could be the goal of *al-hajah* due to some reasons such as its price is affordable compared to Arixtra (P. S. P. MOH, 2018). Moreover, when diagnosed VTE, pregnant women or high-risk women after delivery at least 6 weeks, they are strictly prescribed Clexane. Inexpensive medicine for treatment in a long duration definitely is preferred by any hospitals (Irwan Mohd Subri et al., 2018). Despite economic hardship is not engaging people to *lar'rah* level, nevertheless less cost in term of price of medicine like Clexane will lift the economical burden leads to better compliance and a safe puerperium.

Abdullah (2018) also stated that in spite of the medicine is issued prohibited because of extracted from unlawful ingredients, there are two provisions that need to consider; First, the availability of medicine. If halal alternatives are not existing around, then the prohibited medicine is the best choice to save the lives. Second, the feasibility of medicine. If the halal alternative medicines exist but the price seems too expensive until it become unaccessible to average income group of people which is the majority area under the curve, then the alternatives actually most likely are not feasible.

CONCLUSION

The final conclusion from this research is to recommend a new dimension of fatwa which able to accommodate with recent source on maternal death issue in Malaysia. The new dimension of fatwa is proposed for practicality in Malaysian hospitals which weighing *al-hajah al-shariah* can be a legal parameter in determining Islamic ruling. The need (*al-hajah*) to have preventive medicine eventhough it presents as porcine based medicine which declared by Islamic Jurisprudence could appear as a new contemporary *ijtihad* in epistemic of *fiqh al-waqi'* in Malaysia nowadays.

In fact, this decision will parallize the stance between JAKIM, MNFC and MOH regarding the practice that contrast with fatwa issued. Eventually, it could wipes the confusion out amongst Muslim patients regarding that matter.

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