

CHAPTER V : ANALYSIS AND DISCUSSION

5.1 Introduction

Based on the foregoing findings from both methods, namely documents review and interview in previous chapter, apparently, the statement of Islamic authorities regarding LMWH in Malaysia gives impactful scenario towards the its acceptance and implementation in Malaysian hospitals. The unsolved conflict between the need of O&G department and the misunderstood stance of MCMKI will be everlasting perpetuate if not addressed properly. Because of that, the unfavored anticoagulant namely LMWH owing to its porcine preparation ground may bare-contemplated from *fiqh* perspective even though the decision regarding that anticoagulant had been imposed within ten years ago by MCMKI.

This researcher' opinion indeed, corresponds to the current practices in Malaysian government hospitals especially in O&G department which began to be widely used following its superior potentials offered. Moreover, thromboprophylaxis with LMWH has been permitted by MOH during pregnancy and puerperium for those who are at-risk. In addition to that, the prohibition of LMWH imposed by MCMKI stemming from the existence of Fondaparinux (Arixtra) as halal alternative is also, remains questionable.

The problem arose recently when clinical evidences proved that Fondaparinux has insufficient safety profile for pregnancy and puerperium, which in turn could further harm the fetus inside. This is because of the Fondaparinux's formulation based on merely chemical basis and limited function if it is compared to how the effectiveness of

natural sources works in human body.

Hence, this current chapter set out to examine and scrutinize the degree of the need for thromboprophylaxis with LMWH from *fiqh* perspective with three selected shariah principles; Principle of *istiḥālah*, principle of *ḍarūrah* and principle of *ḥājah*. These *sharī'ah* principles will be analyzed one by one in this chapter following interview data analyzation first.

5.2 Data Analyzation from Interview Method

The researcher will elaborate the data collected from interview sessions received from three different fields; Medical, pharmaceutical and *sharī'ah*. The percentage at the pages 272, 274 and 278 obtained from those three specializations had indicated the average level of agreement upon the main purpose of this research.

It had shown that medical experts' average of assessment is 81%, while pharmaceutical experts displays for 63% as the lowest among of those fields. Apart from that, *Sharī'ah*'s average of assessment is 87% correspond to the agreement of contemporary *ijtihād* recommendation.

Depending on the table 2.3, data from medical providers has been divided into twofold: Firstly, Muslim medical doctor. Secondly, non-Muslim medical doctors. The first three boxes represented non-Muslim O&G specialists named as MS1, MS2 and MS3. They agreed on the entire items in the description given but they were not asked item 4, 6 and 7 because the questions designated for Muslim doctors only.

MS1, MS2 and MS3 strongly agreed that LMWH has been approved to prevent VTE during pregnancy and puerperium following to the recent statistic of maternal mortality has increasing in Malaysia. They also commented that the program of risk assessment upon pregnant and puerperium women has been proven its pertinent to

reduce maternal mortality and shall be offered to those who indicated to it.

“We must take note what are the risk factor. Let say if she is obese, then get score 2 we give them LMWH. So, this score is based on our critical experiences. And then if the patient gets score 3, we don’t question anymore, they must be given LMWH” (MS1).

“Scientific shows the low molecular weight heparin is more effective than unfractionated heparin... and if you use unfractionated heparin after caesarean section, then the risk of hemorrhage you know...hematoma... that means clot blood inside is higher lah after caesarean section”(MS2)

“In the UK, when they did the assessment, only 70% has risk factors that women that died from pulmonary embolism. So, Malaysia is even higher,” (MS2)

“After we started this program in Temerloh, I had not lost any single mother. No mother suffers to death due to VTE” (MS3)

According to MS1, MS2 and MS3, the implementation of VTE Risk program during pregnancy and puerperium with prescribing LMWH upon those who are at-risk have a significant impact for a successful pregnancy. This is supported by Greer & Nelson-Piercy (2005) who reported that out of 61 studies involving 2603 pregnancies recruited thromboprophylaxis with LMWH, there was no maternal death occurrence due to its advantage simultaneously offers less bleeding event (Sakai et al., 2019). Furthermore, it has a potential of predictable response (James et al., 2006) and most importantly it does not cross placenta (H. L. Casele, 2006). Consequently, MS1, MS2 and MS3 emerged at 100% each person for each themes.

Participant named as MS10 practicing in O&G field preferred to use UFH as thromboprophylaxis due to certain reason such as cheapest price rate among all three options of anticoagulant because LMWH can be considered as A class drug. Second reason is, due to its originality which is prohibited religiously in this shariah. Third, many medical officers (MO) used to consume UFH rather than LMWH, so they just directly apply UFH as prophylaxis upon at-risk mothers beginning at score 3. The participant also never experienced any maternal mortality following

thromboprophylaxis with UFH because they are well handling the side effect such as heavy bleeding with protamine sulfate.

According to MS5 and MS6, they found no record of maternal mortality in their hospitals attributed to the implementation of thromboprophylaxis with LMWH as assessed as moderate risk (score 3) during pregnancy and low risk with score 2. Nevertheless, both do not agree with the parameter shariah-medic during risk evaluation due to their own opinions:

“I thought, it just one of yardstick to know whether patients need heparin or not. Ok, there are many situations where low molecular weight heparin is needed. If let say it is not intended for mothers’ life, then it really wanted to save baby’s life. Some people have SLE for example or anti phospholipids syndrome. As I said earlier that the blood easily to clot in the venous. That situation does not need score sheet. As we diagnosed that, immediately we will be giving low molecular weight heparin” (MS5)

“Thromboembolism is catastrophic disease which can cause death suddenly. It does not have halves situation. So, I don’t know how to say that...” (MS6)

Generally, MS5 and MS6 had been classified as repulsive to the parameter which integrate shariah and medical because their preference is more prone to take into account of previous experiences in dealing with VTE patients, instead of stick to a guideline alone. However, they agreed with the objective of this research in achieving a contemporary solution in tandem with *fiqh* point of view pertaining to promulgate decision on LMWH during pregnancy and puerperium. Below is the clear stance forwarded from MS6;

“I strongly agree. I support it. My colleagues said, ‘That too old, I thought MCMKI is a bit left behind, probably due to some hurdles...’” (MS6)

Besides, when MS4 been questioned regarding the probable relationship between dramatic rise of maternal mortality and patients’ refusal upon ingredient of LMWH, he suspected that, his preference is not referring to that refusal factor alone but

most likelihood caused by another unknown factor. The last three boxes from medical provider data represented by MS7, MS8, MS9 with their specialities are cardiology, haematology and family medicine, respectively. Their specialization also used to prescribe LMWH in order to prevent and treat the patients who are problematic with heart attack and cancer sufferers. They highly recommend the decision being reviewed because the decision imposed in 2009 often lead to misconception amongst doctors, pharmacists and public.

“As for me, the wording is a bit problematic because it indirectly stops people from discussing for further issue. I hope by having statistic about maternal death which is alarming nowadays due to VTE in Malaysia and the existence of risk factors, people will start to eye-opening. It really hurts when our record on maternal death due to VTE is higher than our neighbour countries. Due to that, I thought we need to open the discussion again. Wallahu’alam. Probably, the most appropriate wording for this matter is to be allowed for darurat cases. It’s clearer and understandable.” (MS7)

“If there is no directive from top management, that’s will be happening. This issue clearly similar with vaccine issue. People are getting confused.” (MS9)

However, according to MS10, without denying the effectiveness and safety profile in LMWH, MS10 responded that the decision by MCMKI regarding the prohibition of LMWH is well understood and never dispute about that kind of anticoagulant.

Throughout the medical data obtained, the researcher found out another two factors are contributing to the *hifz al-nafs* of the mothers and unborn babies, they are firstly, the cost of the anticoagulant and secondly, the implementation of the VTE Risk Assessment itself. Both variables have been mentioned by each participant.

The researcher observed that, if the LMWH status is judged as permissible from MCMKI or JAKIM but the expenditure budget on LMWH become a huge hurdle to

implement in each state, this research at least had put forward an effort to prove that Islam, indeed provide a comprehensive way to solve the problem as al-Imām Al-Suyūṭiyy (1983) mentioned *idhā ḍāqa al-amru, ittasaʿa, waidhā ittasaʿadāqa* means “When a matter is narrowed, it becomes wide and when a matter is too widen, its shall be narrowed.”

Hopefully the cases of maternal mortality will be reduced attributed to the implementation of Risk VTE assessment which was provided by the MOH, however, this research, indeed harmonizes the flexibility of shariah when referring to the effective preventative medicine in pregnancy, as the pregnancy itself is the risk to get VTE as mentioned on page 67. Following this *fiqh* view in proposing the permissibility of LMWH usage, the standpoint has placed an influential impact on Muslim medical doctors to treat the mothers who are prescribed with LMWH and at the meantime, honouring this religion with no avail of guilty feeling due to nonexistence of official supports from Malaysian Islamic authority.

As the data shown in the table 2.4, PE3 accepted to answer the first question only and being repulsive to answer certain questions about the eligibility of women during pregnancy and puerperium to be prescribed LMWH if grouped as mother at-risk because those questions are not related to his speciality. In fact, he asserted that he did not hold the opinion of LMWH made through *istiḥālah* process because LMWH has been fractionated from heparin and never being purified.

“We do not talk DNA issue herein! This is what we call wrong address, unless using blood and flesh. This is about chemical agent which resulted from that material. That’s what we saw. Sometimes people do not understand and just believe what others said. So, this is incorrect. Academic lying! At least we need people who expert in this field. Even, doctors don’t learn about this field. They just know patients. When patients asked

about the medicine, they just replied, 'the medicine is ready,'. Just use and don't know what the ingredient of the medicine is!' (PE3)

PE3 also opined that decision regarding LMWH for VTE treatment and prevention in 2009, indeed never propel any misunderstanding to the citizens. While another two pharmaceutical experts agreed to the objective of this research to figure out the most appropriate anticoagulant due to current demand especially in O&G cases but SP3' stance clearly contrary to both of the pharmaceutical experts.

Despite PE1 agreed for items coded, yet, he refused to accept that LMWH had undergone *istiḥālah* process. In fact, according to him, porcine DNA is not concerned in LMWH prohibition because its basis still regarded as unlawful source. This opinion regarding the prohibition of LMWH totally identical to PE3 in this regard.

"It did not change at all! It just like a band, you cut it into pieces but it still a band. That means it contains DNA. If the DNA belong to human, it is human. If DNA belongs to monkey, then it's a monkey. If DNA belongs to porcine then it is a porcine..." (PE1)

Nevertheless, while PE1 and PE3 refused to accept that LMWH is having no residue of porcine DNA following the process of manufacturing, on another hand, PE2 did pose a different view which is positively accept *istiḥālah* concept in medicines.

"In other word, the new element that produced in the last stage cannot be traced its raw material. The hukum must be independent. However, according to Syāfi'iy madhhab and Yusuf al-Qaradāwī, initially I have contradicted opinion with him but then when I read again, actually I am with him...the concept of istiḥālah do has its basis in Al-Quran..." (PE2)

"If istiḥālah concept being applied today, numerous problems solved. For example, for gelatine manufacturing. Then, settled one problem. That my answer." (PE2)

It is notable to observe that data collected from pharmaceutical experts indicates that integrated shariah-medic parameter for pregnancy and puerperium assessment is

supported by two experts; PE1 and PE2 with respectively 75% and 100%. PE3 can be classified as the opponent of the purpose of this study in which he totally denied the need of LMWH for medical prevention and treatment of VTE disease nowadays stemming to the fatwa in 2009 is absolutely understandable.

Further, table 2.5 displayed the data collected from shariah experts which received through two methods; Firstly, focus group. Secondly, purposive interview which handled in person with the interviewees. In the focus group method, there are two shariah experts involved in that shariah workshop situated in Institut Penyelidikan dan Pengurusan Fatwa Sedunia (INFAD), USIM. Both experts answered the items coded on the paper following listening and discussing the questions directly.

Based on the answer given on the paper, S8 and S1 considerably agreed with all items coded except the item which stating that moderate risk can be justified as *al-ḥājah tunazzal manzilah al-ḍarūrah* which equivalent to minimum *ḍarūrah* from *fiqh* perspective. S8 firmly stressed that moderate risk during pregnancy can be deemed as *al-ḥājah tunazzal manzilah al-ḍarūrah* without named it as minimum *ḍarūrah* while S1 opined that VTE is a life-threatening disease for pregnant and puerperium women, so whoever evaluated and classified as at-risk patients for VTE event, then they are considered as *ḍarūrah* immediately owing to prescription and supervision from medical experts.

Furthermore, there are six shariah experts had been interviewed in-person for this research. Based on the data, S3 and S6 did not verify the status of medicine DNA and does not go through *istiḥālah* as permissible as Shafi'ite sect has held it.

“Istiḥālah must be determined through opinion sects, for instance, Shafi’te sect refused to verify it as istiḥālah tammah or not as they consider istiḥālah managed to occur in three or four cases only... right? Wine turn to vinegar, deer blood changed to perfume and animal skins that had been tanned. Even though the definition for this matter is not

too exact, but that is what regarded in shafi'ite sects' books. So, we need to assume that that kind of istiḥalah (regarding the examples given) is prominent in Shafi'ite sect" (S3)

However, after S3 had been clarified that the Enoxaparin Sodium went through the process of biotransformation, S3 matched this preventative medicine for VTE with the case of China bone *fatwā* which decided that *istiḥālah* process is intolerable in the manufacture of China bone or at least LMWH may be considered as *istiḥālah nāqīṣah*.

"In LMWH case, if we use istiḥālah nāqīṣah...maybe it's tolerable" (S3)

Nevertheless, S3 fully supported Enoxaparin Sodium to be used for this time being owing to its efficacy. This justification used in LMWH issue like the insulin for diabetes status beforehand. It is bearable for temporary, rather than permanent application.

"In Malaysia context, Shafi'ite sect officially declared as principal opinion in determination of legal rule, so most of the issues deductively imposed based on Shafi'te sect of thought. So, any products either medicine or cosmetic or ceramic or anything, so long the raw sources is filth or severe filth or intermediate filth and then being processed to a new form, this production is not shariah compliance. DNA or not DNA is the second question. The main question is the originality of sources, because Shafi'ite sect justify based on the source, instead of the final product." (S6)

Resting on that stance, S3 more inclined to refuse *istiḥālah* theory in deriving legal rule, yet the least type that perhaps could be tolerable is *istiḥālah nāqīṣah* while S6 limited the definition and stance of *istiḥālah* straightforward to Shafi'ite view. As presented earlier on the page 164, Shafi'ite sect does not consider *istiḥālah* as a device of legal rule except in few cases with human intervention (Al-Shīrāziyy, 1992).

In turn, the rest of the participants held the view that *istiḥālah* and *istihlak* are valid purification tools over impurity items as shown below;

“If we see istiḥālah and istihlak, they are not approved in the sight of Shafi’ite sect of view but Imām al-Nawawiyy from Shafi’ite sect approved that unlawful flesh if cooked and dissolved completely can be regarded as permissible to eat because the filthy traces had decomposed in the pot. Imām al-Nawawiyy said, when there is human flesh dropped in the pot and it dissolved as it drops into 2 qullah of water, it’s not regarded as filth if there is no single changing in terms of odour, colour and taste. If we observe Imām al-Nawawiyy’s view in this matter, it seems considered the concept of istiḥālah and the food can be eaten if it is edible. If it is medicine, its level is higher than eating. For sure, medicine is allowed, even min bāb al-awlā” (S2)

“If we test the medicine in lab and we found porcine DNA helic, then we call the transformation that occurred is istiḥālah nāqisah. How about istiḥālah tammah? Istiḥālah tammah when the transformation occurs wholly, from fruit to wine, wine to vinegar. When we test vinegar in the lab, we found no more DNA helic inside it, then it is called istiḥālah tammah. In that situation, products with porcine DNA is regarded istiḥālah nāqisah” (S7)

“Physically, if DNA is not detected, for me it is not a problem to be used.” (S4)

Based on above-mentioned scripts, it is clearly to conclude their stances which more inclined in accepting *istiḥālah tammah* immediately declares their preference of Hanafite and Malikite schools of thought. This principle is supported by Al-Dusuqiyy (n.d.) sect who make *qiyās al-musāwah* and the basis of ‘illah as their main justification in determining the legal ruling.

The most controversial issue amongst shariah scholars when it came to integrate between shariah and medical aspect based on CPG and Manual Training 2018. Shariah experts in this research were divided into two groups; firstly, the group that agree to a justification that LMWH is permissible based on *ḍarūrah* principle upon women whom are at risk of VTE either high risk or moderate risk because VTE can be classified as a life-threatening and catastrophic incident.

“We go back to specialists. Usually, specialist doctor will put the method of ḍarūrah, right? As public people, we do not put hajah and darurah in one category, it just well-known amongst jurists. Others don’t know about that. So, it just called ḍarūrah. Do we need hajah as a category? There are scholars who interpret hājah as ḍarūrah. The need turns to ḍarūrah, no more hājah” (S7)

*“I thought it considered as *ḍarūrahif* in this case. If it affects lives, supposedly fall into *ḍarūrah* level. Can cause to lost lives means already included as *ḍarūrah*. So, it is *ḍarūrah*, not *ḥājah* anymore” (S3)*

*“The term to propose to review fatwa must be clear and I suggest VTE around pregnancy and post-partum deemed as *ḍarūrah* ...” (S1)*

The researcher observes that this first group more prone to justify VTE is categorized as catastrophic event during pregnancy and postpartum, in turn, LMWH supposedly judged as permissible based on *ḍarūrah*. In fact, *ḍarūrah* argumentation is easily understood by civilians including medical experts or women at-risk. Besides, *ḍarūrah* is *rukḥṣah* from Allāh upon Muslim to accommodate necessities which threaten human' lives. Consequently, Muslim are indeed, allowed to use *ḍarūrah* justification without guilty in honoring this *sharī'ah*.

Nevertheless, second groupsuch as S4, S2, S8, S6 are on preference to segregate the risks of VTE according to their level of adversity. For example, LMWH is deemed as *al-ḥājah tunazzal manzilah ḍarūrah* during pregnancy, instead of ordinary *ḥājah* for instance;

*“If the risk just little lower than *zan* category, it supposedly be deemed as *al-ḥājah tunazzal manzilah al-ḍarūrah*” (S4)*

*“We clearly understand that moderate risk is totally not same with high risk. In that case,LMWH can be regarded as *al-ḥājah tunazzal manzilah al-ḍarūrah*” (S2)*

S2 argued that LMWH could be proposed as permissible preventative medicine stemming from its classification of *istiḥālah tāmmah*. Indeed, *istiḥālah tāmmah* is allowable from *fiqh* perspective. However, based on his experience as one of state *muftī* in Malaysia, S2 emphasized that, in term of the implementation (*tatbīq*) of legal ruling in Malaysia, more cautious way is favored to uphold this *sharī'ah* with a great respect.

He personally preferred to opt the cautious standpoint to be declared as a guideline for civilians in order to avoid misuse the term of *ḍarūrah* amongst public in which may result to be too lenient with the legal rule in *sharī'ah*.

Another two shariah experts opined that the adversity of moderate risk level is not considered as certainty as high-risk level for mortality incident. In another word, the complication out of moderate risk supposedly less harm compared to high-risk. This is supported in CPG which segregated each risk group according to their level of severity mode of complications.

“Moderate risk can be considered as al-ḥājah tunazzal manzilah al-ḍarūrah. So, may be this group of risk can use other alternative first, even though proved the alternative may cause bleeding event, yet it is not confirmed to cause fatal yet, right?” (S8)

“This one (moderate risk), I thought it still ḥājah. Need to confirm first eventhough it has reached ghalabah al-ẓan at 80%. In fact, it is still not diagnosed yet. Also, it is not confirmed yet... right? Now, yes..the high risk is the highest level.... however, ḥājah itself can ranked as ḍarūrah either specific or general. So, the legal rule for it still same. From hukm perspective, ḥājah still can be considered as legal principle to allow unlawful sources in medical cases.” (S6)

It is explicitly mentioned by S6 that, even though LMWH put forward as *al-ḥājah tunazzal manzilah al-ḍarūrah*, the implementation of LMWH can be regarded as *darurah* either. However, in the opinion of S6, the *fatwā* of LMWH in 2009 is not lead to any misconception. Rather, the medical doctors shall undergo the course specifically of *ḍarūrah* boundaries in order to have the capability to explain upon patients.

Regarding the codification under parameter theme, integrated parameter between shariah and medical risk assessment of VTE during pregnancy and puerperium, there are consensus of agreement achieved from all shariah experts. This is because, the parameter will assist shariah scholars and medical experts to indicate the level of risk severity of the risk. For example, high risk can be regarded as *ḍarūrah*. Moderate risk

considered as *al-ḥājah tunazzal manzilah al-ḍarūrah* and low risk can use *qāʿidah fiqhiyyah kullu rukḥṣah ubīḥat li al-ḥājah, wa lam tustabāḥ qabla wujūdihā*.

While during puerperium, women who get score 2 equivalents to low risk shall be offered LMWH according to their risk. If in this period, the mother got score 2 but without any complications, then she did not require any pharmacological treatment like LMWH, if she scored as 2 points with caesarean section either elective or emergency, then prophylaxis will be continued for 10 days more. Nevertheless, if she gets better after 10 days given LMWH in first round following delivery with complication, then LMWH treatment as prophylaxis shall be ended up. The parameter can be seen the further page in this chapter either.

The researcher would like to emphasize that *ḥājah* here meant *asal-ḥājah tunazzal manzilah al-ḍarūrah* which included in the *ḥukm* of *ḍarūrah* too. They are putting forward *ḥājah* principle accordance to the decision of expertise in O&G who are regarded as *ahl al-khibrah* in this issue. The parameters conform the stratification of the risk group mothers provided by MOH. This is supported by Al-Salmiy (2005) that *muftī* must refer and discuss with *ahl al-khibrah* in the particular area in order to know in detail about the subject matter such as the issues of medical and economy. Meanwhile, Yūsuf Al-Qaraḍāwiyy (n.d.) clarifies explicitly that a *muftī* shall inquiries and collects all the data from *ahl al-dhikr* or *al-khābir* beforehand in imposing *fatwā* process.

In conclusion, resting on the data foregoing mentioned, the researcher observes that shariah experts' stances can be united under a principle of *ḍarūrah* to the usage of LMWH as thromboprophylaxis during pregnancy and puerperium instead of principle of *istiḥālah* which inclined to spark contentious amongst the scholars in Malaysia.

Therefore, the researcher favored to stress that LMWH is allowed during *ḍarūrah* with

particularize *hājah* for moderate risk mothers as opined by Dr Wahbah al-Zuhayliyy in his *fatwā* as presented in the result chapter.

5.3 Cohen's Kappa Analyzation

In qualitative methodology, expert validity and reliability of the data is considered as paramount in research phase. Validity refers to the appropriateness, meaningfulness, correctness and usefulness of the researcher's conclusion while reliability means a concept of consistency and stability of a measurement of the questionnaire on certain time (Kamarul Azmi Jasmi, 2005).

Several measurements had been used to improve validity and reliability as recommended by Bogdan & Biklen (n.d.). The researcher employed the experts' verification process for recommendation of contemporary *ijtihād* with using integrated model shariah-medical. Confirmation of experts is a vital step in ensuring no biasness in academic research.

For this study, verification is measured with using's Kappa index. It means the indicator to determine levels of interrater agreement (Jacob Cohen, 1960) whereby the calculation process as following:

Table 2.6: Formula to calculate using Cohen's Kappa (Source: Cohen, 1968)

$K \text{ (Kappa Value)} = \frac{(P_{\text{rated}} - P_{\text{expected}})}{N - P_{\text{expected}}}$ Key: P_{rated} = number of agreed coded data P_{EXPECTED} = 50% of the number of coded data expected to be agreed upon N = total number of coded data measured for agreement

The measurement of Cohen's Kappa analysis can be seen through following indicator:

Table 2.7: Cohen's Kappa Indicator on Level of Agreement (Source: (Kamarul Azmi Jasmi, 2005))

Indicator Value	Cohen's Kappa Value
Very high	>0.90
High	0.70 - 0.89
Average	0.30 – 0.69
Low	<0.30

Once the parameter which integrate medical and shariah data is established, the researcher provides a set of evaluation forms for shariah experts' approval. The assessment form has seven major items which represent the description of the proposed *ijtihad* regarding the usage of LMWH based on its risk group during pregnancy and puerperium. Spaces also provided for the experts to note down their comments or recommendations.

Table 2.8: Experts Evaluation Form

No	Item	Yes	No
1.	Thromboprophylaxis with LMWH is a necessarily needed (<i>ḍarūrah</i>) because the rate of maternal mortality related VTE is majorly leading in Malaysia currently.		
2.	Risk Assessment of VTE- KKM 2017 is classified as <i>ḍarūrah</i> based on <i>qā'idah fihiyyah</i> namely <i>al-ḍarar yuzāl/Lā ḍarar wa lā ḍirār</i> .		
3.	Women in pregnancy and puerperium whom are at risk is prioritized to have thromboprophylaxis with LMWH, porcine based anticoagulant based on <i>qā'idah fihiyyah</i> <i>dar'u al-mafāsīd awlā min jalbi al-maṣāliḥ</i> .		
4.	The high-risk group (score 4 and above) is classified as necessarily needed (maximum <i>ḍarūrah</i>) for thromboprophylaxis during pregnancy and puerperium based on <i>qā'idah fihiyyah</i> namely <i>Al-ḍarūrah tubīḥ al-maḥzūrah</i> .		
5.	The moderate risk (score 3) is classified as tenacious need based on <i>qā'idah fihiyyah</i> namely (<i>al-ḥājah tunazzal manzilah ḍarūrah</i>) equal to minimum <i>ḍarūrah</i> for thromboprophylaxis during pregnancy and puerperium.		
6.	The low risk (score 2) in puerperium with complication such as caesarean and obesity permit thromboprophylaxis with LMWH to those women and classified as tenacious need		

	based on <i>qā'idah fiqhiyyah</i> namely (<i>al-hājah tunazzal manzilah al-darūrah</i>).		
7.	Low Risk (score 1, 2) during pregnancy and puerperium whom are not at risk of VTE required to continue non-pharmacological prophylaxis is classified as ' <i>azimah</i> , instead of <i>rukhsah</i> based on <i>qā'idah</i> namely <i>kullu rukhsah ubīhāt li al-hājah lam tustabāh qabla wujūdihā</i> .		
COMMENT:			
SIGNATURE:			
POSITION:			

The expert's panellist (EP) had been appointed to verify the contemporary recommendation from *fiqh* perspective. They are Dr Setiawan bin Gunardi (EP1), Dr Rosli bin Mokhtar (EP2). Their respective institutions and positions as follow:

Table 2.9: Details of intercoder the integrated medical-shariah parameter of this research

No	Name	Institution	Expertists
1	Dr Setiawan bin Gunardi	Faculty of Shariah and Laws, Universiti Sains Islam Malaysia (USIM).	He is currently a senior lecturer at Faculty of Shariah and Laws, Universiti Sains Islam Malaysia (USIM) Nilai. He has been teaching for 5 years officially in USIM and 5 years in other places. He has been involved in teaching Shariah course more than 10 years.
2	Dr Rosli bin Mokhtar	Faculty of Shariah and Laws, Kolej Universiti Islam Selangor (KUIS).	He is currently a lecturer at Faculty of Shariah and Laws, Kolej Universiti Islam Selangor (KUIS), Nilai. He has been teaching for 17 years in Shariah courses.

Through the data verified by the two experts, the researcher calculated the score with using Cohen's Kappa' formula as mentioned above to determine their level of approval on the proposed recommendation. The results and findings of the experts' verification will be elaborated further.

5.4 Findings of the Study through Cohen's Kappa

The result of the expert assessment shows that the integrated medical-shariah parameter of using LMWH as porcine base anticoagulant during pregnancy and puerperium reaches 1.000 agreement, namely the average (mean) Cohen's Kappa level measurements obtained from both EPs. This data indicates that a very high level of approval as presented in table 2.7, agreement of Cohen's Kappa Level. Below are the elaborations on each specialist validation on the parameter.

Table 3.0: Verification for Integrated Medical-Shariah Parameter of Using LMWH, porcine base anticoagulant as thromboprophylaxis during Pregnancy and Puerperium

No	Item	EP1	EP2
1.	Thromboprophylaxis with LMWH is a necessarily needed (<i>ḍarūrah</i>) because the rate of maternal mortality related VTE is majorly leading in Malaysia currently.	√	√
2.	Risk Assessment of VTE- KKM 2017 is classified as <i>ḍarūrah</i> based on <i>qā'idah fiqhiyyah</i> namely <i>al-ḍarar yuzāl/ lā ḍarar walā ḍirār</i> .	√	√
3.	Women in pregnancy and puerperium whom are at risk are prioritized to have thromboprophylaxis with LMWH, porcine based anticoagulant based on <i>qā'idah fiqhiyyah dar'u al-mafāsīd awlā min jalbi al-maṣāliḥ</i> .	√	√
4.	The high-risk group (score 4 and above) is classified as necessarily needed (maximum <i>ḍarūrah</i>) for thromboprophylaxis during pregnancy and puerperium based on <i>qā'idah fiqhiyyah</i> namely <i>Al-ḍarūrah tubīḥ al-maḥzūrah</i> .	√	√
5.	The moderate risk (score 3) is classified as tenacious need based on <i>qā'idah fiqhiyyah</i> namely (<i>al-ḥājah tunazzal manzilah ḍarūrah</i>) as similar as minimum <i>ḍarūrah</i> for thromboprophylaxis during pregnancy and puerperium.	√	√
6.	The low risk (score 2) in puerperium with complication such as caesarean and obesity permits thromboprophylaxis with LMWH such as Clexane to those women and classified as tenacious need based on <i>qā'idah fiqhiyyah</i> namely (<i>al-ḥājah tunazzal manzilah al-ḍarūrah</i>).	√	√
7.	The low risk (score 1, 2) during pregnancy and puerperium who are not at risk of VTE required to continue non-pharmacological prophylaxis is classified as <i>'azimah</i> , instead of <i>rukḥṣah</i> based on <i>qā'idah</i> namely <i>kullu rukḥṣah ubīḥāt li al-ḥājah lam tustabāḥ qabla wujūdiḥā</i> .	√	√

Cohen's Kappa Level of Agreement	1.000	1.000
Overall Level of agreement	1.000	

Based on the table 3.0 entitled expert's evaluation form, EP1 and EP2 agreed on the entire items proposed. As both EP1 and EP2 from shariah specialization, they comprehend the principle of *ḍarūrah* and *al-ḥājah tunazzal manzilah al-ḍarūrah* in seeking medical treatment with unlawful sources particularly upon pregnancy and puerperium women.

The statistic of maternal mortality published by Department of Statistic of Malaysia on 2016/2017 (DOSM, 2017) is a significant evidence in which both EPs agreed that thromboprophylaxis with LMWH is categorized as *ḍarūrah*. According to EP1, the description supposedly to be more exact and clearer with removing the details of the Risk Assessment of VTE. In the first place, the researcher wrote down that:

“Risk Assessment of VTE- KKM 2017 such as High-risk (score 4 and above), moderate risk (score 3) and low risk (score 1 and 2) is classified as ḍarūrah based on qā'idah fiqhiyyah namely Al-ḍarar yuzāl/Lā ḍarar walā ḍirār.”

However, EP1 suggested to remove the descriptions of the risk assessment to be as below:

“Risk Assessment of VTE- KKM 2017 is classified as ḍarūrah based on qā'idah fiqhiyyah namely al-ḍarar yuzāl/ Lā ḍarar walā ḍirār.”

EP1 also inquired for the item no 3 regarding the *qā'idah fiqhiyyah* namely *dar'u al-mafāsīd awlā min jalbi al-maṣāliḥ* given. The researcher elaborates that the

masalih here means to seeking the halal medication for pregnant and puerperium women and at the same time to observe the religion of using halal material, while *mafsadah* means maternal mortality.

Both EPs were clarified that according to the data from medical specialists, moderate risk (score 3) shall be started thromboprophylaxis with LMWH while high-risk (score 4 and above) require immediate thromboprophylaxis with LMWH. Inform consent is still forwarded to the patients, however majority of the patients including Muslims put trust on medical doctors' advice if their condition based on their previous experiences. With that information, both EPs agreed for item no 3, 4, 5, 6 and 7.

EP2 really depend on the principle of *istiḥālah tāmmah* in which it can be consumed, provided the medicine has no residual of porcine DNA anymore. He opined that it is sufficient to justify the legal rule of LMWH with *istiḥālah tāmmah*, rather to make principle of *ḍarūrah* and principle of *al-ḥājah tunazzal manzilah al-ḍarūrah*. However, he understood the nature of Malaysian lifestyle which very sensitive with regard to porcine base product. In the end, he agrees that LMWH can be justified as permissible with *ḍarūrah* principle for those who at risk.

5.5 Conclusion

In conclusion, the proposal of integrated medical-shariah parameter of using LMWH during pregnancy and puerperium had been validated by appointed experts and has reached 1.000 equivalently to very high according to Cohen's Kappa index. According to the comments received from both experts, the parameter will assist *muftis* in making decision due to VTE during pregnancy and postpartum.

The integrated medical-shariah parameter concurrently from another aspect may be an academic proposal to MCMKI to review the current decision issued in 2009 due

to maternal mortality caused by VTE ranked as principal killer recently. With that, the researcher completely assessed the data obtained from interview session, validated the integrated medical-shariah parameter by Cohen's Kappa formula and finally verified by *Shari'ah's* experts.

5.6 Determination of Islamic legal rule on LMWH based on *Istihālah*

Istihālah is not regarded as determinant of legal rules in Malaysia religious affairs unless in few natural ambits only stemming from a concession in Shafi'ite sect. Doubtless to state, religious authorities in Malaysia opts to bind opinions with Shafi'ite sect of in practicing daily jurisprudence legal rules, even though there was no mentioned in official statement in Malaysian Federal Constitutions with regard to any single *madhhab* adoption except Perlis which stating that "Islam as a state official religion by following *Ahli Sunnah Wal Jamaah*", instead of any single *fiqh* *madhhab* (Md Nor et al., 2019).

However, the researcher decided to use *istihālah* as secondary justification despite religious authorities in Malaysia refuted it owing to certain reasons such as may cause to commercial turmoil due to misuse of conglomeration between halal and haram.

5.6.1 Analysis of *Istihālah* and *Istihlāk* Process of LMWH

With respect to the second research question of this research, it was found that *istihālah* and *istihlāk* may be able to enlighten and answer it. Equivalently, *istihālah* is biotransformation process, which transforming from originality crude heparin tissue to salt or sodium. According to the LMWH (Enoxaparin Sodium) manufacture which can refer at appendix 1, the principle of *istihālah* can be traced at the chemical step of purification process while *istihlāk* be highlighted at the process of precipitation.

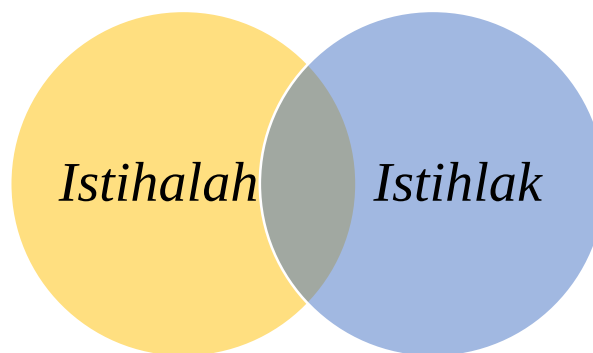


Figure 3.9: The removal process of DNA porcine step formed through *istihlāk* and *istiḥālah* process.

As displayed in the figure 3.9, the overlapping part revealed with the process of purification and precipitation steps manage to merge at the same process but in separate steps. It is clearly understood that *istiḥālah* in LMWH manufacturing means transformation from crude heparin into pure heparin through two chemical steps namely, oxidation and decoloring treatment. Whilst, *istihlāk* process can be traced at the process of precipitation in which eliminating the impurities elements from heparin completely by degrading and digestion process.

Another step of *istihlāk* process occurs at the stage of depolymerization from high molecular weight into low molecular weight heparin which depolymerizing 24 polydisaccharides to be partial disaccharides. In term of chemistry discipline, Enoxaparin sodium which undergoes a complete depolymerization would lead to only simple disaccharides and its efficacious would be affected. While form *fiqh* perspective, the degradation and decomposition process can be similarly evaluated as *istihlāk* concept.

Subsequently, the *istiḥālah* process was figured out at the step of transforming crude heparin into liquid form, which may be considered as incomplete biotransformation (*istiḥālah nāqishah*). As far as *istiḥālah* is concerned here, the important element in *istiḥālah* requirement is called as conversion agent namely

hydrogen peroxide which was added to strong base anion exchange resin column (*Method for Producing Enoxaparin Sodium by Using Crude Sodium Heparin Products*, n.d.). It plays a vital role. Then, after going through the converging process, the DNA is eliminated during precipitation step in turn, and immediately indicates that *istiḥālah tāmmah* had undertaken the process.

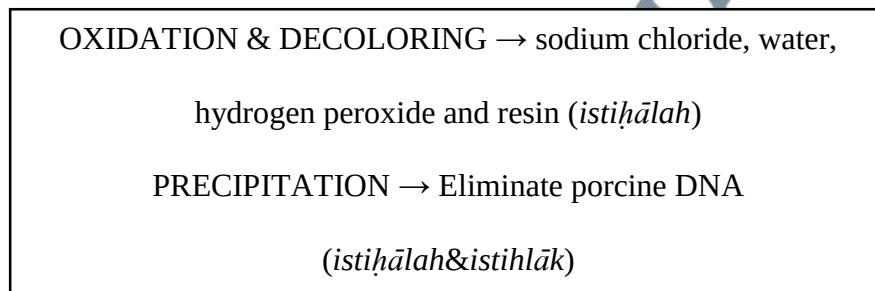


Figure 4.0: Purification process of porcine DNA removal

Figure 4.0 is the simplified purification step of porcine DNA removal process from *fiqh* perspective. This purification process posed a pivotal step in determining the legal rule status of LMWH, either can be argued as *istiḥālah tāmmah* or vice versa especially the DNA removal step. Without this purification process, LMWH merely can be regarded as *istiḥālah nāqishah* which opposed to *istiḥālah tāmmah* from *fiqh* point of view. On the hand, *istiḥālah nāqishah* in this case is translated as a transformation process from crude heparin into drug substance, yet still having residual of porcine DNA. Consequently, it will affect the law of the subject matter and its implementation.

The pure heparin sodium produced after the step of precipitation as shown in the flow chart reveals the Enoxaparin manufacturing process (appendix 1). The mucosa tissue from porcine intestine was initially in solid form has changed into liquid at oxidation step. Oxidation step was carried out after salt hydrolysis formed. Due to that, the researcher can relate that the transformation of the physical mucosa tissue of porcine

began when oxidation step taken place.

Further, below is the checklist of *istiḥālah* prerequisite in justifying the LMWH legal rule;

Table 3.1: Checklist of *Istiḥālah* Prerequisite

Sample/ product	<i>Istiḥālah</i> steps checklist	Type of <i>Istiḥālah</i>	Justification
Low Molecular Weight Heparin: Enoxaparin Sodium	1. Raw material		Accessibility
	2. Conversion agent (Porcine DNA Removal):	<i>Istiḥālah Tāmmah</i>	Feasibility
	- Oxidation		Efficacy
	- Decolorization		Safety Profile
	3. Final Product		
Islamic legal rule on LMWH (Enoxaparin or Clexane)		Permissible	

Based on the table 3.1, the researcher analyzed the prerequisite of Enoxaparin manufacturing process; either conforming *istiḥālah tāmmah* or not. For example, does the process of *istiḥālah tāmmah* has halal conversion agent even though the raw material is produced from forbidden sources? As analyzed in the table 3.1, the legal rule of LMWH can be easily declared as permissible because it fulfills whole requirements of *istiḥālah tāmmah*. Lawful legal rule resulted from fulfilling the prerequisites of *istiḥālah tāmmah* in products is supported by some jurists for instance Al-Zayl'iyy, (1897), Ibnu Qudāmah (1997), Ḥammād (2004).

To date, there are two certificates from accredited laboratories by JAKIM confirmed that there has been no residual of porcine trace or element found in Enoxaparin sodium which represented as LMWH group in this research. The first

certificate issued in 2015 carried out by TPM Biotex laboratory and most recent certificate in 2019 performed in UKM Unipex laboratory. TPM Biotex laboratory released the result of percentage of nucleotide impurities as well as protein impurities remains in that LMWH while UKM Unipex mentioned that Enoxaparin Sodium (Clexane) has no residual porcine DNA only without further details mentioned.

Throughout this analysis, the most obvious finding to emerge from the analysis is that the discovery of DNA code in products is prime significant to impose on Islamic law of any products as emphasized by Izhar Ariff (2015) either halal or haram even though porcine protein and nucleotide impurities still exist in LMWH. It is interesting to note that in the determination status either *haram* or *halāl*, the investigation on the subject matter is encouraged to not too bog down in the details owing to a doctrinal of straight jacket by uncovering the widespread of prohibited or *shubhah* items which eventually may end into phases of difficulties to derive a legal rule. This stance also supported by S7 during interview session with him;

S7 (2019)	<i>“When we test vinegar in lab, then we found no wine chain (DNA), it is called istiḥālahtāmmah. To date, we always found products with porcine DNA which may be called istiḥālahnāqīṣah. My observation is muftis in Malaysia don’t hold that view, may be one or two states muftis do not hold such opinion. They just observe the whole product without examining meticulously on DNA and the sort because they opined to a dalīl ‘al-aṣlubaqa ‘mākāna ‘alāmākāna’. If they examine in depth, all prohibited elements will have uncovered. That is why in scientific field...aa..whenI engaged to halal certification research, scientists will investigate three levels only namely steps 1, 2 and 3. Step 4 they will find prohibited element. So, it is better to end up our investigation at that phases only. That opinion is held by some mufti and Dr Yūsuf Al-Qaraḍāwiyy. But, madhhab al-Shafi’iyy is more prone to hold extra caution or ihtiyatstanpoint. In conclusion, for me, we need to understand first istiḥālah tāmmah and nāqīṣah.”</i>
-----------	---

The researcher’ finding with regard to *istiḥālah* might be contradicted to the

stance decided by MCMKI in 2009. As most of the chores and interactions practiced in Malaysia adhering firmly with Shafi'ite sect of thoughts, the most appropriate methodology in deriving legal rules used by Malaysia Muslim scholars which is suitable to its social and culture is the concept of *al-istiṣḥab* (Tuan Sidek & Rizwan, 2017).

Nevertheless, the researcher views that this inconsistency situation can be encountered in order to achieve the harmonization between this research and the implementation of the ruling in Malaysia by using the guideline of permissibility of unlawful sources of medicines under *istiḥālah* process which can be practiced by *shari'ah* scholars and Muslim medical doctors either as adapted from 'Abdul Rab (2018) study on guideline of using unlawful sources in cosmetic;

Table 3.2: Guideline of using unlawful sources in medicines under *istiḥālah* process. (Illustrated by the researcher)

Num	Detail of Guideline	Tick
1.	The end product had been changed from filthy material such as porcine, wine, carcass or blood into new form of medicines which is clean, pure and completely different from the original physical form.	
2.	The process of <i>istiḥālah tāmmah</i> occurs from filthy material into new form of medicines with ensuring all the criteria of the original form including odor, color and taste removed totally by physical examination. That is considered complete transformation.	
3.	If the final products do not fulfill <i>istiḥālah tāmmah</i> in the manufacturing process, further principle that would be the amplest to justify the usage of unlawful sources in medicine is principle of <i>ḍarūrah</i> or principle <i>ḥājah</i> .	
4.	If the final products do not fulfill <i>istiḥālah tāmmah</i> in the manufacturing process, <i>ghalabah al-ḍan</i> to attain the benefits of the product is another provision to be observed in the <i>ḍarūrah</i> and <i>ḥājah</i> time.	
5.	Any medicine which formulated from unlawful sources and not undergo the process of <i>istiḥālah</i> can be used for physical treatment instead of oral intake when <i>ḍarūrah</i> or <i>ḥājah</i> times.	
6.	The usage of the product after undergone <i>istiḥālah</i> process does not affect bad effect or any harm to the patients due to the original material is prohibited as stated in hadith: “ <i>La darara wa la dirar</i> ”.	

The items in the guideline above (Table 3.2) can be considered as significant elements that need to be checked out to decide the permissibility of medicines which had undergone *istiḥālah* process in Muslim countries. It is supported by recent shariah scholar, Al-Jal'ud (2008) who recommend the prescription of medicine to Muslim patients to be given according to the hierarchy of prioritization which begin with the halal medicine. If the *halal* medicine does not pose efficacious and less safety data, then the medicine which had been undergone the process of *istiḥālah tāmīmah* is prioritized.

If that choice is not able to treat effectively, then the doctor should find the less haram medicine although not undergone *istiḥālah* process compared to a medicine contains dominantly *ḥaram* ingredients. If the less haram sources medicine still poses bad effect to the patients, then the last option is to consume the haram medicine even though it is *ḥarām li dhātihi* to cure patients.

That hierarchy constructed by Al-Jal'ud is indeed, similar with the checklist provided above, instead the guideline below focuses directly to medicine which had undergone *istiḥālah tāmīmah* as the first option of medical doctors in prescribing medicine which manufactured from unlawful materials.

According to guideline of *istiḥālah*, it clearly shows that, transformed substitute under the principle of *istiḥālah tāmīmah* is indeed deemed as legal tool in LMWH manufacturing process. The medicine which does not undergo the process of *istiḥālah* completely or classified as *istiḥālah nāqishah* on another hand, another principle should be used as mentioned in the guidelines such as principle of *ḍarūrah* and *ḥājah*.

Overall, the researcher views that most *fatwā* organization and prominent scholars more prone to consider *ḍarūrah* and *ḥājah* principles to allow thromboprophylaxis with LMWH, rather than principle of *istiḥālah* and the researcher thought that the term verdict (*sīghah*) of decision by MCMKI shall be revisited to add

ḥājah situation, instead of *ḍarūrah* only.

Based on the principle of *istiḥālah tāmmah*, the researcher contemplates that it is pertinent to apply *qā'idah* of *takyīf fiqhiyy* as comprehended by Islamic *fiqh* sects, Hanafite and Malikite in pharmaceutical field even though that stance has less enthusiasm for MCMKI regarding substance of LMWH's status. In addition to that matter, following *qā'idah fiqhiyyah* that held firmly by Hanafite sect which asserts that *al-aṣlu fī al-ashyā' al-ṭuhūr ḥattā yadullu al-dalīl 'alā al-najāsatihi* means the origin of everything is permissible until there is legal proof to indicate it is impure (Ibnu Nujaym, 1999).

Moreover, 'Izzat al-Ghanānim (2008) also supported this thought with his data that the result of smoke/steam from burning process of filthy material is carbon dioxide (CO₂) or water hydrogen (HO₂). Experimental research even approved that the water itself have no residue of any manure or feces.

Hence, this research does not intend to blame the decision made by MCMKI regarding *istiḥālah* stance because there is still relevancy due to the situation of Malaysia as Islamic country and guarded by law officially. The relevance of the stance can be observed as extreme caution (*iḥtiyāt*) as well-known method held firmly by Muslim Malaysian scholars. It is noteworthy that, method of *iḥtiyāt* is yet reliable to be implemented, concurrently blocking any evil intention towards porcine trading for commercial purpose (Mahaiyadin et al, 2017).

However, the researcher views that in this new modern era can be deemed as timely initiative for Malaysian *sharī'ah* scholars to accept *istiḥālah tāmmah* as legitimate tool to impose *fatwā* in Malaysia which is aligning with current rapid change. This stance is favorable for the researcher academically with limited to merely pharmaceutical issue, not including food or cosmetic sector.

To conclude, the implementation of *istihālah* concept in pharmaceutical sector supposedly not to create problems as highlighted above, either as commercial interest or in political turmoil because its implementation should be supported with the guideline/checklist in using medicine which undergoes *istihālah* process. In fact, this solution may solve many problems in pharmaceutical sector nowadays. This proposal may be applied temporarily till the whole Muslim world able to lead the pharmaceutical sector without any single prohibited derivatives.

5.7 Determination of Islamic Legal ‘Rule on LMWH based on the Principle of *Ḍarūrah*

Prior studies have noted the definitions of *Ḍarūrah*, the researcher observes that the term of *Ḍarūrah* can be concluded into two stratifications namely ‘fear to be destroyed’ (*khawfu al-halak*) and ‘destroy’ (*halak*) (Qāsim, 1993, Mubārak, 2003). It is necessary here to clarify exactly what is *Ḍarūrah* meant based on *fiqh* point of view. While a variety definition proposed for the term of *Ḍarūrah*, this research will use the preferred term by the researcher as elaborated on the page 193. In visualization, the two stratifications can be viewed in the following diagram;

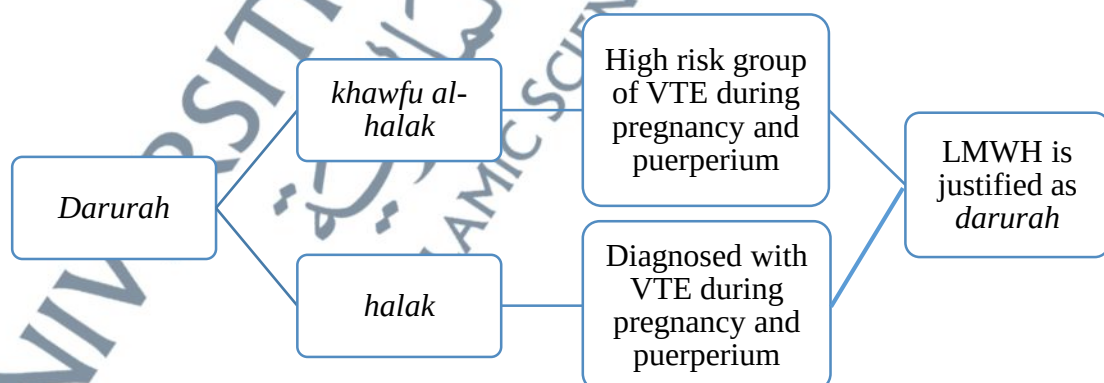


Figure 4.1: *Ḍarūrah* definition based on *fiqh* point of view. (Researcher’s analysis)

The figure 4.1 revealed the scope of *Ḍarūrah* from *fiqh* perspective which

clarifying that the state of ‘fear to be destroyed’ runs parallel with the state of ‘destroy’. Throughout researcher’s examination, *khawfu al-halāk* is proposed to be dissected for women with high risk of VTE during pregnancy and puerperium while *halak* deliberated for those who had been diagnosed as VTE sufferers by clinicians. Both states are stratified as *ḍarūrah* level which highly recommended to be treated with LMWH either for thromboprophylaxis or therapeutic treatment.

It is thought that the suitable term to translate *khawfu* is fear. Some early jurists defined *ḍarūrah* term as *khawfu al-halāk* to fall into destruction (Al-Dusuqīyy, n.d., Al-Jaṣṣāṣ, 1992). However, that feeling of fear should have a reasonable justification which can be expressed as near or close for complete destruction of occurrence. The solid justification in medical cases can be based on medical experts’ experiences (Yūsuf Al-Qaraḍāwīyy, n.d.) stemming from a detail surveillances with *ghalabah al-ẓan* calculation (Al-Shanqīṭīyy, n.d.). Another concrete and accurate justification obtained through risk factors for VTE using score sheet provided by the MOH (MOH, 2014).

As a matter of fact, the high-risk group dissected as *khawfu al-halak* at the expectation of *ghalabah al-ẓan* which equivalent to 51% until 99% that VTE could be to occur. While symptomatic patients whom had been diagnosed as VTE patient are regarded as *halak*. The VTE patients are quantified as 100% as equivalent to calculation of *yaqīn* or certainty degree.

That analysis has been supported by Mohd Hapiz (2016) in his Ph.D. dissertation which mentioned that early *ḍarūrah* level can be justified with symptoms appear to the patients such as paralysis (at hand or leg), bleeding (external or internal), dizzy, mumbling, the body begun to weak, wheezing, abdominal pain, decreasing level of consciousness or uncontrolled saliva. In that case, patients without symptoms but categorized as high risk patient, the *fiqh* level is lower than symptomatic patient.

In the discipline of medical, risk factor is defined as “an agent or situation that is known to make an individual or population more susceptible to the development of a specific negative condition” (Farlex & Partners, 2009). Due to that, at-risk pregnant and postpartum women required to adhere to the CPG recommendation for preventative and management purposes. Based on Cohen Kappa’s analysis, high-risk group mothers are supposedly to be stratified as *ḍarūrah* and to receive thromboprophylaxis with LMWH as indicated by CPG.

Indeed, the eligibility of prevention of VTE during pregnancy and puerperium with using LMWH for high-risk mothers are best elaborated under the *qā’idah fihiyyah* namely *al-ḍarar yuzāl* and *al-ḍarūrah tubīh al-mahzūrah*. In fact, cases requiring prophylaxis for high risk group of VTE, it should be prioritized (*min bāb al-awlā*) because of the potential harm for both fetal and maternal complications as mentioned by Bates et al., (2016).

Furthermore, the current available CPG and Training Manual 2018 in the management and prevention of VTE during pregnancy and puerperium may be considered as *ahl al-dhikr* or *ahl al-khibrah*. The CPG has highly recommended for the high-risk mother (VTE score 4 and above) including the moderate risk patients (VTE score 3) to utilize the prophylactic treatment LMWH such as Clexane or Tinzaparin even though it is porcine in origin. There is an urge to use the recommended medication as it has been proven to reduce the risks of VTE incidences, morbidities and mortalities due to VTE and better motherhood safety.

5.7.1 The Necessity of *Ahl Al-Dhikr* or *Ahl Al-Khibrah* in Thromboprophylaxis for Obstetric Related VTE.

Shariah scholars delineated in determination of Islamic legal rule, the jurists

should acquire for experts' verifications and advices with regard the details and specific features about the subject matter, for instance, in medical cases, the doctors deemed as *ahl al-zikr* or *ahl al-khibrah*. The same practices putatively to be performed in order to understand in other disciplines like linguistic or Shariah studies (Al- 'Awdah, n.d.).

In Islam, the opinion from the experts and scholars (*ahl khibrah*) are reliable and verified to justify a reasonable statement upon any *fatwā* issued. It is mentioned in the Holy Quran:

وَمَا أَرْسَلْنَا مِنْ قَبْلِكَ إِلَّا رَجَالًا نُوحِيَ إِلَيْهِمْ فَسْأَلُوا أَهْلَ الذِّكْرِ إِنْ كُنْتُمْ لَا تَعْلَمُونَ

Meaning: "And We sent not before you except men to whom We revealed [Our message]. So, ask the people of the message if you do not know."

(Al-Quran. Al-Nahl 16: 43)

"أَهْلَ الذِّكْرِ" in that Holy verse translated as "people of the message" literally. That verse explains the previous *ahl al-kitāb* is the member of the books message. It was also quoted that Mujāhid said from Ibn 'Abbas he said; the meaning of *ahl al-dhikr* is *ahl-kitāb*. Similarly, in the surah Al-Anbiyā' verse 7 which referred *ahl-zikr* as the members of the books (*ahl al-kitāb*) (Islamweb.net, n.d., Majma' Al-Fiqhiyy Al-Islāmiyy Al-Duwaliyy (2006). While Ibnu al-Qayyim Jauziyyah (2002) interpreted the verse as command from Allah upon those who do not have knowledge to what he or she follows. In fact, Allah slanders those who merely emulating their previous kinsman in worshiping idols without knowledge.

وَمَا أَرْسَلْنَا مِنْ قَبْلِكَ إِلَّا رَجَالًا نُوحِيَ إِلَيْهِمْ فَسْأَلُوا أَهْلَ الذِّكْرِ إِنْ كُنْتُمْ لَا تَعْلَمُونَ

Meaning: "And We sent not before you, [O Muhammad], except men to whom We revealed [the message], so ask the people of the message if you do not know."

(Al-Quran. Al-Anbiyā' 21: 7)

The term of *ahl al-dhikr* in this verse is referred to previous *ahl al-kitāb*. However, it had been interpreted based on the method “consideration is granted to the generality of the language, not to the specificity of the reason for revelation” (*al-‘ibrah bi umūm al-lafẓ lā bi khuṣuṣi al-sabab*). Ibn ‘Aṭiyyah mentioned that *ahl al-dhikr* denoted to any expertise whom are knowledgeable in their field. Thus, *ahl al-dhikr* here are also referred as *ahl al-ikhtīṣāṣ* in his field or specialty which means the expertise or the specialist in their fields.

According to the Al-Salmiyy (2005) in the provision by a *muftī*, any *fatwā* should not be issued unless refer and discuss with *ahl al-khibrah* in the related area in order to know in detail about the subject matter such as the issues of medical and economy. Yūsuf Al-Qaradawīyy (n.d.) elaborated succinctly that a *muftī* shall inquiries and obtains all the data needed to *ahl al-dhikr* or *al-khabīr* to impose a *fatwā* according to few Quranic text such as Surah al-Naḥl verse 43:

وَمَا أَرْسَلْنَا مِنْ قَبْلِكَ إِلَّا رِجَالًا نُوْحِيَ إِلَيْهِمْ فَسْأَلُوا أَهْلَ الذِّكْرِ إِنْ كُنْتُمْ لَا تَعْلَمُونَ

Meaning: “And We sent not before you except men to whom We revealed (Our message). So, ask the people of the message if you do not know.”

(Al-Quran. Al-Naḥl 16: 43)

وَلَا يُنَبِّئُكَ مِثْلُ خَبِيرٍ

Meaning: “And none can inform you like (one) acquainted (with all matters).”

(Al-Quran. Fāṭir 35: 14)

وَإِذَا جَاءَهُمْ أَمْرٌ مِنَ الْأَمْنِ أَوِ الْخَوْفِ أَذَاعُوا بِهِ وَلَوْ رَدُّوهُ إِلَى الرَّسُولِ وَإِلَى أُولِي الْأَمْرِ مِنْهُمْ لَعَلِمَهُ الَّذِينَ يَسْتَنْبِطُونَهُ مِنْهُمْ

Meaning: “And when there comes to them information about (public) security or fear, they spread it around. But if they had referred it back to the Messenger or to those of authority among

them, then the ones who [can] draw correct conclusions from it would have known about it.”

(Al-Quran. Al-Nisā' 4: 83)

Therefore, the term of *al-khabīr* is synonym to *ahl al-dhikr* and *ahl al-ikhtisāṣ* and it is used interchangeably. Referring to the matter regarding the management of VTE, the MOH consists by a team of experienced and knowledgeable medical consultants whom studied and produced a guideline related to VTE management and its prevention during pregnancy and puerperium is classified as *al-khabīr*. Thus, in legal rule process of LMWH to furnish at-risk mothers surround pregnancy and postpartum apparently acquire their opinions and experiences.

5.7.2 High Risk Group (Scored 4 onwards) of VTE During Pregnancy and Puerperium

The optimal approach in obstetric VTE management is thromboprophylaxis with using LMWH for high risk group (scored 4 onwards) as suggested in CPG. This recommendation may be considered as necessarily required, although at the level of prevention in the virtue of *ḍarūrah* situation. Sultan et al (2013) found that women in pregnancy and in puerperium whom having any risks as stated in high risk group in the manual training are indeed necessarily needs for thromboprophylaxis with Enoxaparin as they highly exposed to higher harm (*muḍar*) if the patients are not treated with prevention dose of LMWH.

Among of the research figured out, “VTE developed in four of the 186 (2.2%) who received thromboprophylaxis, and in 31 of the 283 (11.0%) who did not (HR of VTE, 0.13; 95% CI, 0.04–0.40)” (Barbar et al., 2010). This mean, patients who not recruited with thromboprophylaxis more likely to have VTE compared who not.

The fearsome of complication out of VTE is mortality owing to blood clot lodged in artery and blocking the blood flow system to the lung. Below is the figure displayed about interlink between the complication that might occur following none or suboptimal preventative medicine towards this catastrophic event.

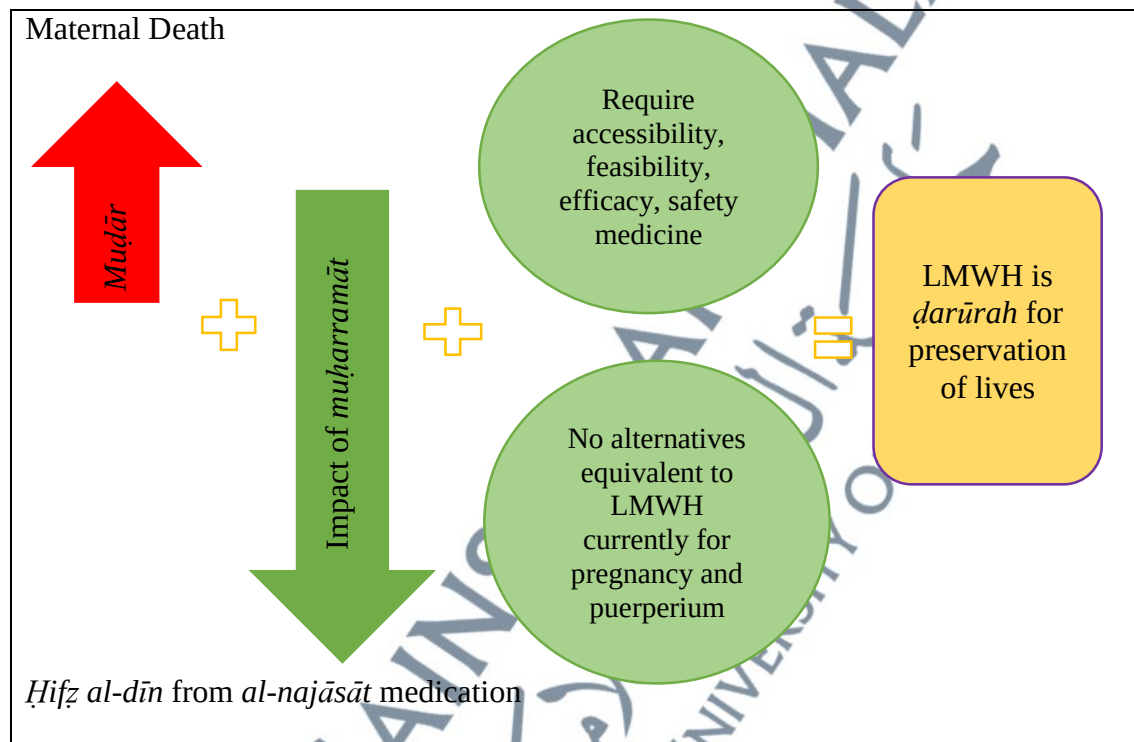


Figure 4.2: The diagram shows the impact emerges out of the risks calculation of using LMWH added with medical condition demand. (The researcher's analysis)

Figure 4.2 showed that there are two situations emerged out of using porcine base anticoagulant in obstetric VTE. The first arrow in red color named as harm (*muḍār*) or maternal death increased while the second arrow in green represented an impact of using *al-muḥarramat* in medication, whereby the rights of religion preservation (*ḥifẓ al-dīn*) cannot be attained at ultimate level. This is because a patient required to cross the rights of *ḥifẓ al-dīn* due to the need to consume LMWH necessarily due to obstetric VTE.

Nevertheless, in this never-ending dilemma, there are another two factors which enforcing medical doctors' decision in prescription namely; firstly, the superiority of preventive medicine including accessibility, feasibility, efficacy, safety medicine. Secondly, the alternative to replace LMWH for VTE patients are limited, added with the paucity of relevant high-quality research to include pregnant or puerperium women as experimental sample is considered unethical to be carried out.

Thus, the evidences are based from reviews of pool of statistic data, comparative studies and observational researches globally. Sufficient informations obtained as many guidelines have recommended the superiority in efficacy, and safety profile of porcine base LMWH anticoagulant such as Clexane in prevention of VTE for pregnant women and puerperium. Therefore, justification on flexibility or *rukhsah* among Muslims should be considered over LMWH decision should be re-contemplated.

The eligibility of high-risk group to be recruited with LMWH as effective pharmacological prevention owing to a supported information from RCOG (2015) that previous VTE occupied 24.8 as adjusted odd ratio (AOR) for VTE incidence over other risk factors concurrently positioned high-risk group of mothers as *darurah* level in Islamic law (The AOR can be viewed in the table in appendix 6). This study accentuated the MOH' focus to pave their concentration on those who had had previous VTE or history of VTE as high-risk group to be given LMWH over other risks.

In a nutshell, from *fiqh* perspective, the researcher inclined to concur that high-risk group of VTE during pregnancy and puerperium most likelihood situated in the degree of *ghalabah al-zanor* quantified at 51%-99% for maternal mortality implication if the effective pharmacological preventive is not undertaken appropriately as recommended by the MOH. Because of that, the situation of high-risk mothers can be stratified as *khawfu al-halak* due to earlier discussion regarding *darurah* in scope.

5.8 Determination of Islamic Legal Rule on LMWH based on the Principle of *Al-Ḥājah Tunazzal Manzilah al-Ḍarūrah*

According to the decision by MCMKI in 2009, it mentioned that LMWH was prohibited due to its source, with exemption on *ḍarūrah* condition. The state of *ḍarūrah* is clearly explained in the previous discussion. Nonetheless, how about moderate risk group of mothers towards VTE? They are not classified as high risk which involved in *ḍarūrah* scope, but they also recommended by CPG to be prescribed thromboprophylaxis with LMWH. Which category of *ḥukm* shall justifies it?

To answer that question posed, the researcher thought that the principle *al-ḥājah tunazzal manzilah al-ḍarūrah* may be considered as the most appropriate of justification for moderate risk group mothers. In another word, the meaning of *ḥājah* in this moderate risk case judged as minimum line of *ḍarūrah* (Mubarak, 2003, Hapiz, 2016) though it does not directly pronounced legally as *ḍarūrah*. In fact, the *qā'idah fihiyyah* namely *al-ḥājah tunazzal manzilah al-ḍarūrah* is a corollary of the *qā'dah kubrā* namely *al-ḍarar yuzāl* ('Abd al-Salām, n.d.). The interlink between both *qawā'id* clearly shows that moderate risk group women who are at risk of VTE indeed, treated as *ḍarūrah* condition.

Nevertheless, re-observing the risk group stratifications outlined in CPG, high-risk (score 4 and above) patients have been prioritized over score 3, in prescribing them with LMWH for prophylaxis. Because of that, the best evaluation from shariah perspective that can be forwarded here, based on the CPG and Training Manual 2018. Moderate term in a layman understanding means less extreme, intense or violent. While, online dictionary Cambridge states that moderate means neither small nor large in size,

amount, degree or strength, for example: a moderate intake of caffeine should not harm you (Dictionary cambridge, n.d.).

From that literal meaning, layman uses it as something that would not harm living things. However, from the data collected from medical participants in this research, most of them agreed that LMWH shall be started off when the patients in pregnancy and puerperium scored 3 points from the score assessment. Following are some of the data regarding that matter:

MS7 (2019)	<i>"I suggest, if CPG stated that moderate risk offer LMWH, then we just follow the CPG."</i>
MS2 (2019)	<i>"Ok, let me explain it this way. The green top guideline, when they describe this, they describe low risk no need. Then intermediate and high risk. Both of intermediate and high risk need thromboprophylaxis."</i>
MS1 (2019)	<i>"We must take note what are the risk factor. Let say if she is obese then get score 2 we give them LMWH. So, this score is based on our critical experiences. And then if the patient gets score 3, we don't pose any question anymore, they must be given LMWH"</i>
MS5 (2019)	<i>"Supposedly we stick to that guideline because it already designated for us. If let say something happen, we do have valid justification. So, it has got to medico-legal implication. The implication of medico legal is there."</i>
MS6 (2019)	<i>"Consider for LMWH means strongly recommended. But, require means need to do. Consider means strongly recommended to prevent that thing (VTE). For me as a practitioner, it is darurat! Must be given. However, if the patient refuses and the risk factor is low score then maybe we can tolerate."</i>

From the data obtained, most of them agreed that moderate risk or intermediate risk should be prescribed with LMWH as stated in CPG. Albeit moderate risk is less violent than high risk factor does but still it still runs parallel in the scope of necessity which is shall never underestimate the crucial state of moderate risk to perceive thromboprophylaxis. This is based on the urge of prevention is better than cure as well

as dependent on a *qā'idah fihiyyah* called blocking the evil is prioritized than perceiving the benefit or in Arabic phrase, “*dar'u al-mafsadah awlā min jalbi al-maṣlahah*” (Al-Suyūṭiyy, 1983).

While that deemed as a corollary from *qā'idah kulliyyah* namely *lā ḍarara wa lā ḍirār* which means if the *mafsadah* emerges was more dominant than *maṣlahah* do, then blocking the *mafsadah*'s occurrence is eligible to be prioritized than attaining the *maṣlahah* (Al-Suyūṭiyy, 1983, Ibnu Nujaym, 1999, 'Aliyy Haidār, 2004).

In conclusion, *qā'idah fihiyyah* namely *al-ḥājah tunazzal manzilah al-ḍarūrah* is arguable to interlink with *dar'u al-maṣlahah awlā min jalbi al-maṣlahah* in the case of prevention of VTE during pregnancy and puerperium with LMWH for moderate risk group as suggested by *ahl al-khibrah* that are found in literatures and interview data. The *qā'idah fihiyyah* of *dar'u al-maṣlahah awlā min jalbi al-maṣlahah* will be clarified afterward in this chapter.

5.8.1 Moderate Risk with Score 3 during Pregnancy and Low Risk with Score 2 during Puerperium Shall Offer for Thromboprophylaxis with LMWH

The terminology of moderate or intermediate is used in obstetric VTE cases to differentiate from high risk group which is confirmed has greater harm over moderate risk. However, based on the data collected from interview session with medical participants, moderate risk group mothers also considered to be judged as *ḍarūrah* to receive thromboprophylaxis although addressed as minimum in *ḍarūrah* scope while high-risk group mothers dissected as maximum *ḍarūrah*.

Table 3.3: Examples of few risk factors associated with the score point of each risk extracted from the manual training produced by MOH in 2018.

TYPES OF RISK	SPECIFIC RISK	SCORE RISK
Pre-	Medical comorbidities. (e.g. - Cardiac	3

existing	failure, active SLE, active tuberculosis, nephrotic syndrome, diabetic nephropathy, malignancies)	
	Obesity:	
	BMI $\geq 40\text{kg/m}^2$	2
	BMI 30-39 kg/m^2	1
Obstetric Risk	Caesarean section (elective & emergency)	2
	Pre-eclampsia	1

Table 3.3 is an extraction some of the risk factors score taken from risk assessment of VTE published by MOH. Moderate risk is equivalent to 3 points of scoring checked by clinicians with using score sheet Risk Assessment of VTE. In fact, each disease of medical comorbidities such as cancer, cardiac failure and the sort equivalently to 3 points of scoring. The reality of the moderate risk is eligible to *al-ḥājah tunazzal manzilah al-ḍarūrah* ruling since medical experts suggest those who score 3 points considered for thromboprophylaxis. This is based on the situation namely *al-ḥājah al-māssah* (Al-Ashqar, 2001).

5.8.2 *Dar' u Al-Mafsadah Awlā min Jalbi Al-Maṣlahah* in Moderate Risk Group (Score 3) during Pregnancy.

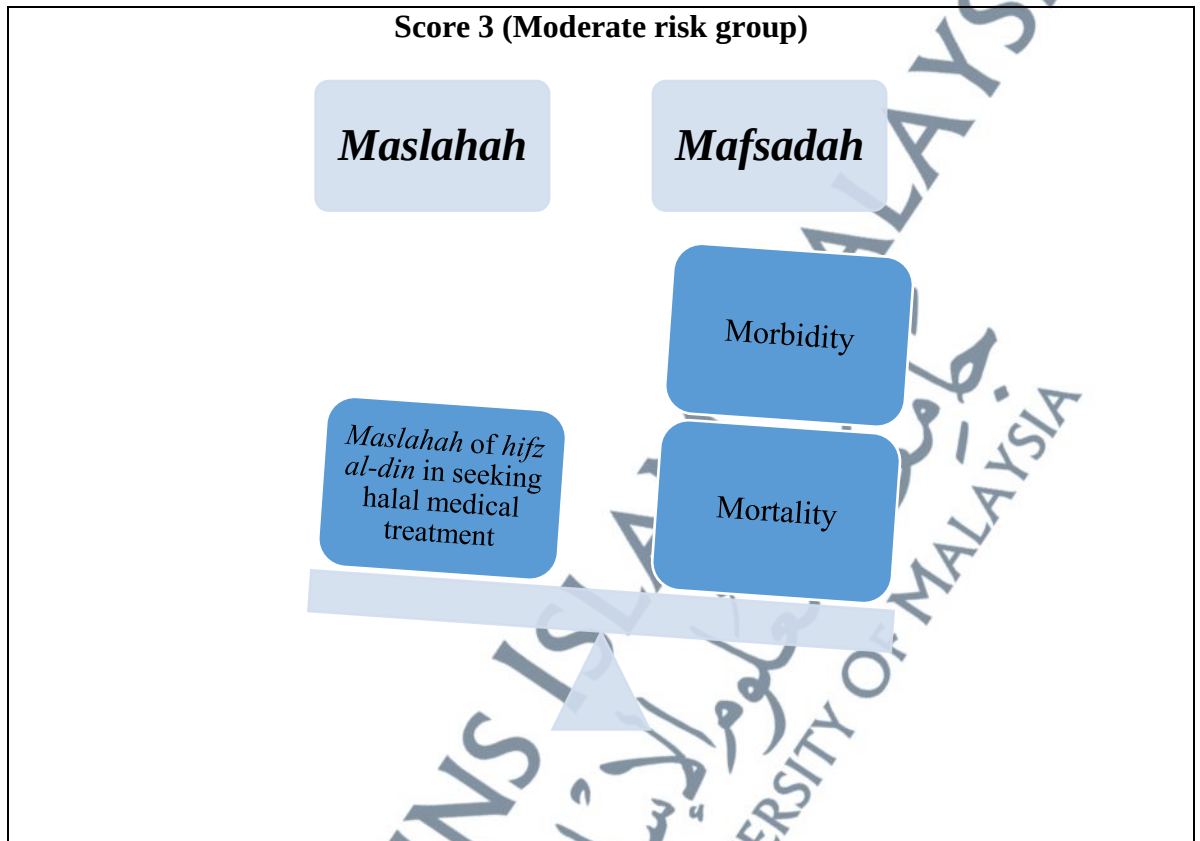


Figure 4.3: The diagram shows the emergence of few *mafsadah* that could occur amongst pregnant women and puerperium without effective preventative medicine. (The researcher's analysis)

Figure 4.3 showed the implications which expected most likely to occur in two elements; *maṣlahah* is translated as right of *hifz al-dīn* will be upheld if seeking the lawful medicine, nonetheless few *mafsadah* might emerge at worst such as mortality and morbidity around pregnancy and postpartum stemming from the usage of inappropriate preventive medicine as not indicated in CPG. There is a large volume of published studies describing that pregnancy itself is the risk of getting VTE due to its normal physiological state (MOH, 2013, Brown & Hiett, 2010). Because of that, pregnant women' condition with all the risk factors either pre-existing types or obstetric risk as shown in table 3.3 will consequently pose greater burden and harm.

In that regard, other than *al-hājah tunazzal manzilah al-darūrah* to justify the moderate risk group of mothers shall be prescribed with LMWH for preventive measures, few other *qawā'id fiqhiyyah* can justify that group such as; First, *dar'u al-maṣlaḥah awlā min jalbi al-maṣlaḥah*, second, *idhā ta'āradat maṣadatani rū'iyaa' zamuhumā bi irtikābi akhafihi mā* and third, *irtikāb akhaffu al-darrayn*.

Those *qā'idah fiqhiyyah* are relevantly to justify the moderate risk group of VTE to receive thromboprophylaxis as prevention due to other significant risk factors such as thrombophilia, lupus, heart disease, sickle cell disease, fluid and electrolyte imbalance, postpartum infection, transfusion, women ages 35 and older (James et al., 2006) scored as 3 or equivalent to moderate risk.

Above all, the consent of using LMWH as thromboprophylaxis also shall be obtained from the patients. The inform-consent form should be succinctly clarified before patients as medical treatment's etiquette. If high-risk or moderate risk group refuses for prophylaxis with LMWH, then best option of anticoagulant supposedly to be offered is UFH. However, the patients should be counseled upon the bleeding risk. It is not so easy to administer as the dosing require hand- handled. That is how the implementation takes place in currently practices in Malaysian government hospitals as described by the medical participants as follows;

MS2 (2019)	<i>"Ok...ok...first of all, counselling...the counselling...my consent form is both in english and malay la..there is in Malay and english....there will be explained as to what their risk? their risk is high.and what are drug available... All right, and if let say there is alternative, they also return the consent the alternative and the alternative is including unfractionated heparin. And... we also explain, but the problem with heparin is of course it comes in pile, twice a day and it's very difficult to train patient to do that. That means, they need to do it before clinic to do it. The patient...as I said, 15% of them, Ok I know the figure wanted to ask their husband."</i>
------------	--

MS6 (2019)	“Researcher: So, in case the patient refuses to consume Clexane, what is the best options that you will prescribe to them? Participant: Ok so far, I didn’t meet such case yet, but if there is, then I will be giving them heparin.”
------------	---

5.9 Integrated Medical-Shariah Parameter to Receive Thromboprophylaxis with LMWH during Pregnancy and Puerperium

Following is the researcher’s analysis regarding the parameter as a contribution throughout this research.

5.9.1 Pregnancy Risk (score 1, 2, 3, 4 and above)

The scoring system during pregnancy notified to start off the thromboprophylaxis at moderate risk which equivalent to score 3 and above. By contrast, puerperium score is slightly different depending on mother’s conditions which can be viewed further in this subdivision. Depending on that scoring system, the integrated Medical-Shariah Parameter uses *qawā’id fiqhiyyah* in justifying the degree of the risk group based on the VTE Risk Assessment and CPG provided by MOH as *ahl al-khibrah* or *ahl al-dhikr* in this field.

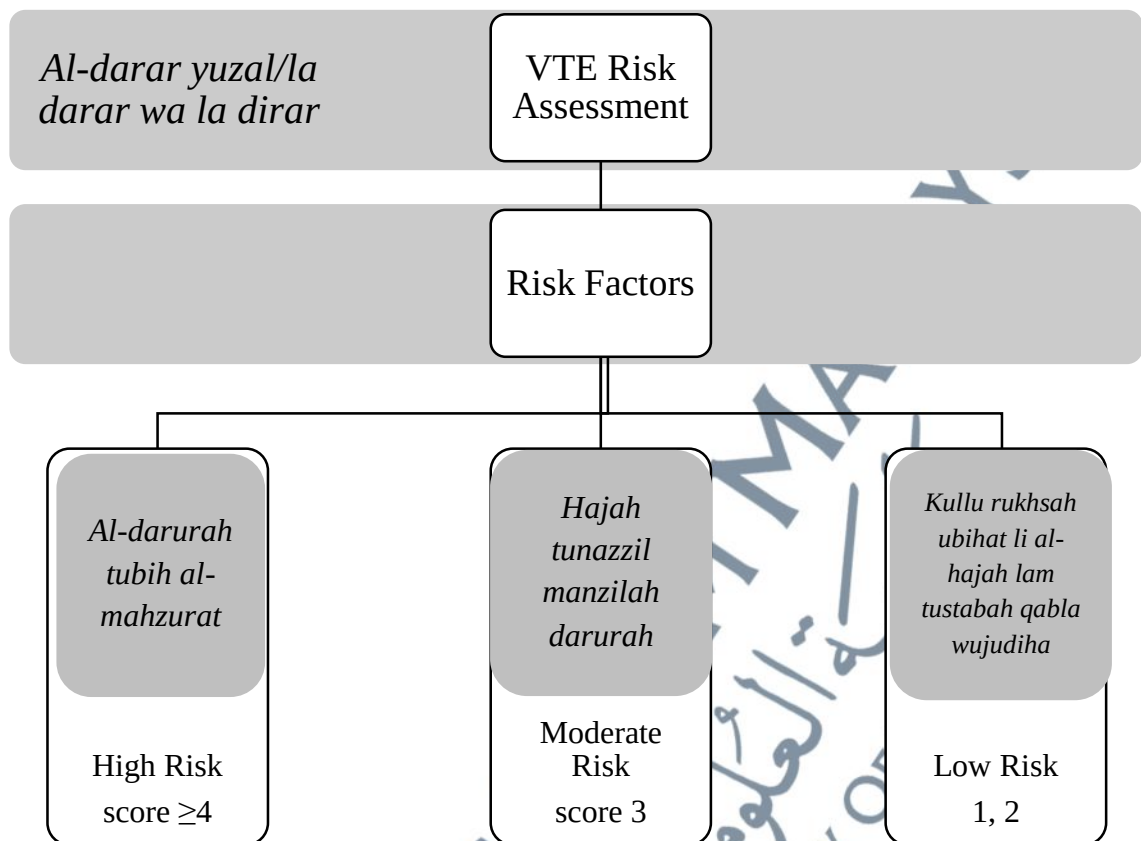


Figure 4.4: Parameter standard to each stage VTE risk assessment in pregnancy with the legal proof in shariah based on *qawā'id fiqhiyyah* on the left side. (The researchers' analysis)

Figure 4.4 displayed each risk group equivalent to each *qā'idah fiqhiyyah* respectively. *Al-darar yuzāl* is justified to this kind of preventative medicine in medical treatment with using porcine anticoagulant to eliminate the harm amongst women whom are at risk. The screening program identify any possibility of VTE risk are obligated during pregnancy and puerperium phases and can be devoted as an effort to remove the harm if the risks identified by clinicians. With that, the risk factors detection in the virtue of *al-darar yuzāl* can be best translated as *dar'u al-maṣlahah awlā min jalbi al-maṣlahah* as eliminating the *mafsadah* that most likely to develop if no properly stratified.

High risk (score ≥ 4) group of VTE especially on pulmonary embolism (PE) which can be classified as lethal condition can be prevented with prompt diagnosis (Ouetllete, 2019). Unfortunately, PE often present with no symptoms which may cause no avail of early diagnosis. On this regard, it can be justified as *al-darūrah tubīh al-mahzūrah* for thromboprophylaxis with LMWH while moderate risk (score 3) is argued with *al-hājah tunazzal manzilah al-darūrah*. While the low risk group during pregnancy will proceed with non-pharmacological medicine as suggested by MOH and the most appropriate *qā'idah fiqhiyyah* for this group is *kullu rukhsah ubīhat li al-hājah lam tustabāh qabla wujūdihā*.

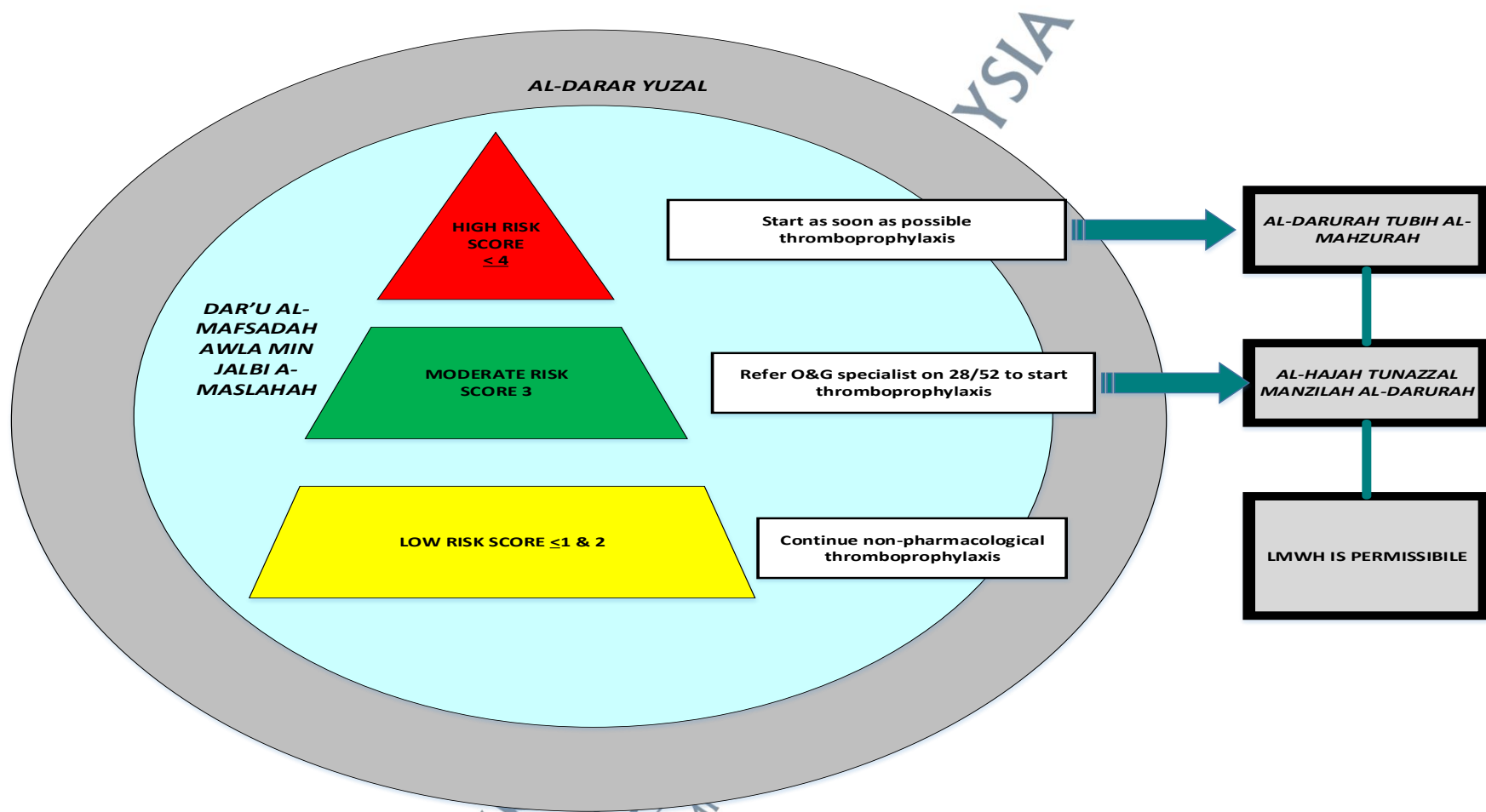


Figure 4.5: The general big picture of parameter of the need of LMWH usage as prevention VTE during pregnancy only. The parameter intended to assist Malaysian *Muftis* to impose *fatwā* regarding VTE related obstetric. (The researchers' analysis)

According to Figure 4.5, the outer circle represents the *qā'idah fiqhiyyah kubrā* namely *al-ḍarar yuzāl* which selected to treat VTE with LMWH. Furthermore, the inner circle displays the phase whereby the screening been performed with scoring sheet upon patients regarding the risks of VTE. Once the risks of VTE emerge according to its level, *qā'idah fiqhiyyah juz'iyah* namely *dar'u al-maḥṣadah awlā min jalbi al-maṣlahah* is proposed as an effort to prevent VTE event. In addition, by weighing all the conditions of pregnant and puerperium women, the researcher agrees to justify the degree of moderate risk group (score 3) as *ḍarūrah* but classified under the *qā'idah fiqhiyyah* namely *al-ḥājah tunazzal manzilah al-ḍarūrah* depending on CPG and data collected from most medical experts. Overall, high risk or moderate risk of VTE during pregnancy and puerperium considered as eligible to be included in the boundary of *rukḥṣah* to be recruited thromboprophylaxis with LMWH.

Broadly speaking, *ḥājah ghayrul mu'tādah* context runs parallel with *ḍarūrah* context. In fact, it is supported by few *qawā'id fiqhiyyah* related which permits forbidden things (*al-maḥẓūrāt*) such as “need permits forbidden, in another hand it means; prohibited is allowed if there is a need which is properly define” which later translated into arabic as *al-ḥājah tubihu al-maḥẓūr, al-ḥarām yubāḥu li al-ḥājah* (Kāfiyy, 2004).

Although few medical experts from certain states in Malaysia disagree to start off the LMWH at moderate risk due to some factors such as costly, originality and many medical officers (MO) used to treat patients with UFH, however majority O&G experts are supporting the prevention and management VTE with LMWH as clarified beforehand.

Based on the data collected from the experts, the researcher views that apart from able to alleviate women' risk of getting VTE, the permissibility of LMWH during

pregnancy and puerperium is better to be aligned with contemporary decision at MCMKI level. This is because the permission from MCMKI viewed as high impact decision to wipe out the dilemma amongst Muslim medical doctors so that their implementation regarding LMWH as imposed in the *fatwā* by MCMKI.

This thought is supported by data collected from majority of medical experts who agreed thromboprophylaxis should begin at onset of moderate risk, instead of high-risk level as prevention from VTE during pregnancy and puerperium as following:

MS7 (2019)	<i>"As for me, the wording is a bit problematic because it indirectly stops people from discussing further issue. I hope by having statistic about maternal death is alarming nowadays due to VTE in Malaysia and the existence of risk factors and a hurting situation when our record on maternal death due to VTE is higher than our neighbour countries, then I thought we need to open the discussion again. Wallahu'alam. Maybe be the most appropriate wording for this matter is to be allowed for darurat cases. It's clearer and understandable."</i>
MS3 (2019)	<i>"That's why I said, my challenge is the word of darurat. Do we need to wait until diagnosed that you have that disease then at that point, you want to start prevention and treatment? Haa... that's how I look at it! Because you do have something to prevent. So, it is better to prevent rather than waiting for it to really happen for giving medicine."</i>

Few medical experts in O&G prefers to opt for UFH due to free from unlawful sources like porcine, in fact they proved there is no maternal mortality along the implementation of UFH as the preventative medicine by managing any side effect due to UFH such as heavy bleeding with protamine sulfate. Nevertheless, most medical experts admitted that the most successful pregnancy of the state's achievement throughout implementation of LMWH when it starts at the moderate risk level concurrently experiences the reduction of maternal mortality.

Among of the states, Sarawak had implemented intensive VTE in obstetric prevention program which emphasizing the usage of LMWH anticoagulant starting

from VTE score 3 and above including VTE score 2 if cesarean section delivery; they do have documented the remarkable reduction of VTE related maternal mortality statistic even though most medical providers had complained that Sarawak's expenditure on tackling obstetric VTE issues with LMWH was approved to be the highest over other states in Malaysia by the MOH. The slides of the reduction of maternal mortality in Sarawak after starting the program of thromboprophylaxis with LMWH such as Clexane can be viewed in appendix 11.

With that, the researcher thought that the most appropriate legal rule for this *ḍarūrah* condition is to make legally permissible over LMWH in the virtue of *rukḥṣah* concentrating during pregnancy and puerperium. Indeed, that explicit *fiqh* solution regarding medical treatment with porcine derivatives creates more harmonic situations and the statement is easily understandable in legal rule.

5.9.2 Puerperium Risk (Score 2)

The awareness and early intervention including prophylactic treatment should be emphasized as the risk factors such as cesarean section and obesity are globally alarming. Hence, there is a tenacious need to emphasize on the usage of LMWH anticoagulant following prompt diagnosis of the risk, although the recommended preventive medicine extracted from porcine intestinal mucosa layer. This is further supported by Al-Suyūṭīyy (1983) who stated that *al-ḥājah tunazzal manzilah al-ḍarūrah* is to permit the prohibition in all aspects either chores, interaction or consumption purpose. It shows that *ḥājah* or the need of certain group of people is defined as a cause to be permissible to use unlawful source of medicine in this VTE case.

Puerperium is a period after delivery and the highest risk to develop VTE events are during this phase. Meng et al., (2014) reported that the definition of puerperium could also contribute to a variety of reported incidence, for instance, two different studies defined puerperium as 12 weeks after delivery while another one defined as first two months after delivery.

Why puerperium is to be proposed as *darūrah* condition? This is because puerperium condition is the continuity of pregnancy state, although there is no longer baby in the womb, the physiological hormones are still there. During this phase many mothers has less mobility as they are resting during confinement. Thus, in term of most likelihood to get VTE is higher especially post complicated delivery and pre-existing risk factors. Literatures reveal that puerperium potential to be at risk of VTE is higher than pregnancy term and daily risk of VTE increases for 15 to 35 fold compared to non-pregnant women (Bates et al, 2016). In fact, MOH (2018) emphasized that mothers who are in puerperium period must be assessed in new assessment particularly those who had some complications during delivery such as caesarean section, instrumental delivery, complicated/prolonged labour, sepsis, eclampsia, PHH.

Therefore, the usage of porcine based LMWH is indeed, thought to be applicable in puerperium with VTE score 2 associated with complication owing to the effective cause or *sabab* to start prophylactic treatment and to prevent greater complications. As clearly stated in CPG and Training Manual 2018, they encourage mothers in pregnancy and puerperium to mobilize in order to avoid dehydration for low risk group as prevention way of VTE.

These low risk group of women (score 1 and 2) are suitable to be justified under the *qā'idahfihiyyahin ḥājah* matters as “every flexibility granted to the need, is

permissible; yet, it does not applicable to all condition which has not happen or any calling to do so” or in Arabic phrase, *kullu rukḥṣah ubīḥat li al-ḥājah lam tustabāḥ qabla wujūdiḥā* (Kāfiyy,2004). Indeed, the low risk mothers whom do not have any risk or symptom of VTE do not require any pharmacological treatment using anticoagulant such as LMWH.

In the case of a mother delivers through caesarean who scored 2 points, that mothers stratified as recommended for thromboprophylaxis with LMWH according to manual training of VTE management. Following is a data obtained from medical expert during interview session:

MS6(2019)	<i>“For example, there was my patient after delivery through caesarean with no complication, she able to move actively, wore the stocking, but then the next morning when her husband pushed her to the toilet with wheel chair, after a while she collapsed,”</i>
-----------	--

That lethal event showed that delivery through caesarean might be proposed to undergo prophylactic preventive medicine like LMWH provided with advices of O&G experts and not hurdled by several factors such as expenditure issue over anticoagulant fund, permission from the patients or family. Some patients scored as 2 points with complications shall be classified as *al-ḥājah tunazzal manzilah al-ḍarūrah* situation even though the score is 2 with certain conditions like obesity or caesarean delivery. They are recommended still to be treated with LMWH still despite only VTE score 2, but because the score was due to a strong indication, they are age recommended for preventive dose of LMWH but in a shorter duration.

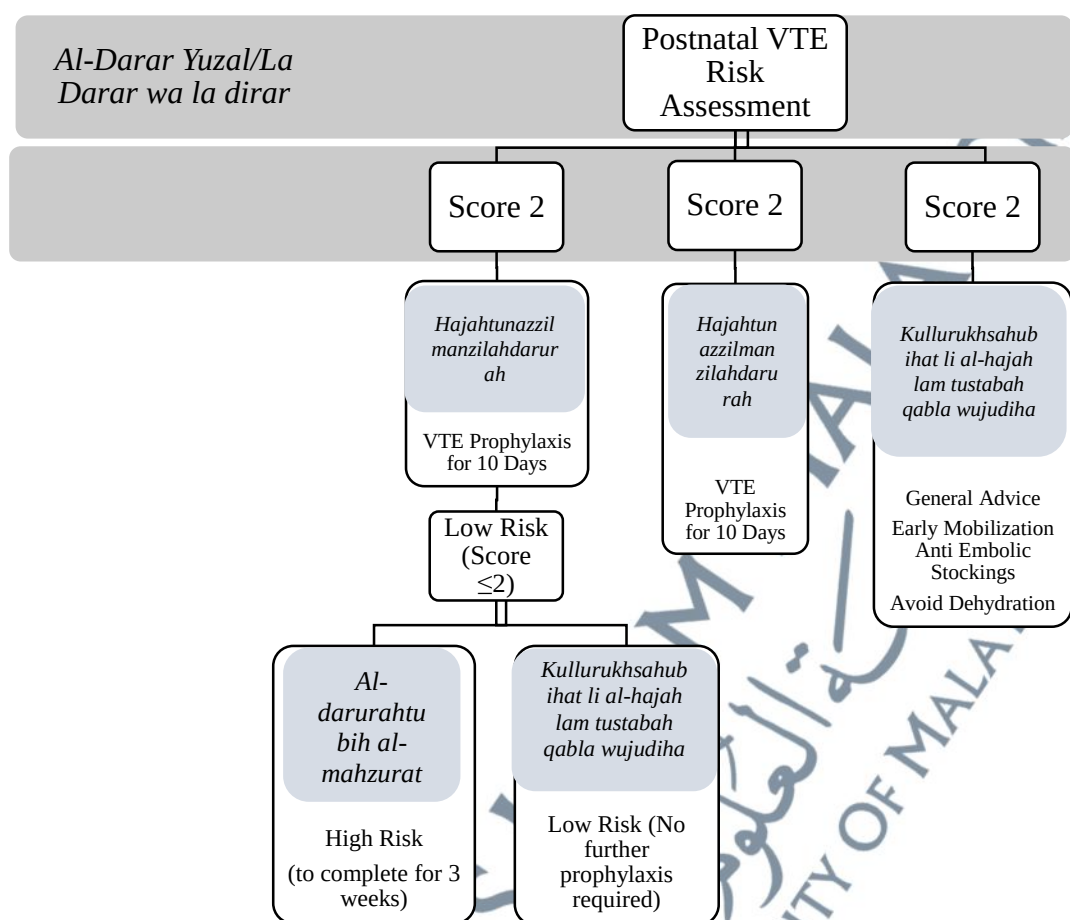


Figure 4.6: Each condition in puerperium or postnatal supported with *qawā'id fiqhiyyah* (The researcher's analysis)

Figure 4.6 indicates *qawā'id fiqhiyyah* which trying to be proposed from researcher's observation regarding puerperium period. Likewise, during pregnancy which risky for VTE, although VTE incidents are not diagnosed yet but the risk factors adequately proved to argue women in puerperium could be placed a necessarily needed group. This is strongly supported by *qā'idah fiqhiyyah* namely *al-ḍarar yuzāl* and *lā ḍarar walā ḍirār* if indicated by medical experts who accountable for the surveillance.

According to the Training Manual 2018, once the women assessed as low risk (score 2), there are three different situations that could occur; First, if the women gave birth vaginally and do not have any complications with no VTE symptoms, then no

prophylaxis with LMWH prescribed. From fiqh perspective, there is no legal cause to recruit prophylactic based on *qā‘dah fiqhiyyah* namely ‘need is a cause of concession’ or in Arabic *al-ḥājah sabab al-rukḥṣah*. Second, women gave birth with complication either caesarean or obesity or aged more than 40 years, then prophylaxis would be prescribed on them. Third, women who deliver and scored as 2 points carrier but with complications, they would be suggested to use prophylactic agent. After ten days on the thromboprophylaxis, if the complication prolonged and the O&G experts advises to continue the prophylaxis and the mothers had an informed consent about implications would develop following its refusal. Further information regarding the ingredients of the prophylactic agent were informed, then the at-risk mothers shall continue the treatment. If the she has no risk at all to cause for thromboprophylaxis, then she can practice her health care as per normal routine. It is judged as *kullu rukḥṣah ubīḥat li al-ḥājah lam tustabāḥ qabla wujudiḥā* in that condition.

A large volume of literature had proved that puerperium is a crucial period to be taken into account for any risk of VTE events. Throughout this research, medical experts had repeated many times that CPG and Training Manual 2018 which provided by the MOH are official reference for their medical practitioners as medical field closely categorized as medico legal area. In other word, those guidelines could justify their decision on patients legally. However, the experiences and opinions of experts also regarded as proofs to perform any action in medical cases, not purported to follow and obey each patient without investigate respective conditions.

5.9.3 Conclusion

In conclusion, the researcher thought the most appropriate proposal regarding thromboprophylaxis towards obstetric VTE group with moderate risk (score 3) during

pregnancy and score 2 with complication during puerperium, they are regarded as *al-ḥājah tunazzal manzilah al-ḍarūrah* to receive the prophylaxis even though with LMWH. This stance is supported by Ḥammād (2004) who mentioned that early jurist such as Abū Ḥanifah, Abū Thūr, Ibn Ḥazm and Shafi'ite sect allowed *ḥājah* to be used as legal justification in medical cases to consume unlawful sources of medicine but specifically under *qā'idah* namely *al-ḥājah tunazzal manzilah al-ḍarūrah*.

