CHAPTER I : INTRODUCTION

1.1 Introduction

A vast chronicle of Islamic tradition has placed great emphasis on diseases and infirmity prevention, not merely assuring the normal function state of physical, mental and social wellbeing. This is translated into an explicit declaration in one of the objectives of shariah (*maqāṣid al-sharīʿah*) namely preservation of lives (*ḥifẓ al-nafs*) (Ibn ʿĀshūr, 2001). Theoretically, the researcher intended to scrutinize the idea of *ḥifẓ al-nafs* and explore in details the meaning of prevention before occurrences in relation to preservation of health (*ḥifẓ al-ṣiḥḥah*), preservation of environment (*ḥifẓ al-bīʾah*) and prevention of dangerous diseases (*ḥifẓ minal-maraḍ al-khatīr*) (Ramli & Mokhtar, 2017, Nurdeng Deuraseh, 2012, Malik, 2015) in tandem to accommodate health promotion in this current millennium.

The Ministry of Health of Malaysia (MOH), had been advocating healthy lifestyle as prevention towards life threatening diseases. Tremendous effort in increasing better access to healthcare facilities, equipped with expertise and advances in treatment and medication. A systematic algorithm and risks stratifications of patients into low and high-risk groups, to allow prioritization of care and treatment effectively to prevent them from further morbidity and mortality following fatal complications. Nevertheless, despite in advanced and contemporary medical era, Muslims health care givers and patients apparently confront with difficult challenges in obtaining the most effective medicine yet, accreditation and verified as *ḥalāl* in every process by Islamic body authority such as Department of Islamic Development Malaysia (JAKIM).

Malaysian government has become a world leader and first pioneer in international hub halal after series of achievements and declared as the world's best model for *ḥalāl* food standard by the United Nation since 1997 (Shahar et al, 2019). This includes halal pharmaceutical market research which reported a historical spurt in market demand, trends and opportunities and forecasted to escalate for the period 2018 to 2025 (*Halal Pharmaceutical Market 2020 Forecast Muslim Consumer Market*, 2020).

Surprisingly, Muslims seems to hesitate in seeking for effective and halal medicines in Muslim consumerism market despite rapid Muslim population growth at 2.9 per annum (Eum, 2009); owing to large number of non-Muslim international companies exporting porcine base medicines and other forbidden ingredients for usage. Among of them are Sanofi-Aventis, Bayer Schering Pharma, GE Healthcare, Watson Pharmaceuticals, Vetter Pharma-Fertigung, Organon, Polisan, Pfizer, Nordmark, Novartis (Abdul Halim Ihsan, 2013).

Products such as food, pharmaceutical, clothes, accessories, dishes, cosmetics are deemed as necessity and considered almost inevitable from any ingredients that is considered as filth (*al-najāsāt*) in Islam such as porcine tissues, carcass, blood and alcohol. Mahaiyadin & Osman (2017) had considered that it is undeniably a widespread hardship (*al-ʿumūm al-balwā*) which is hard to avoid. Furthermore, modern day technologies advancement used in almost every level of the process of unlawful sources derivations, which makes it difficult to identify the origin and purity of a substance as compares to conventional methods. As a result, people will use any available and accessible products in market including the pharmaceutical prescription without suspicion.

As for the year 2013, Muslim and Malay ethnicity represent the largest population by religion and ethnicity in Malaysia with 63.1% which contributes to the largest consumerism decision, and ethical demand consumption driven by *ḥalāl* and *ḥaram* doctrines (Figure 1.1).

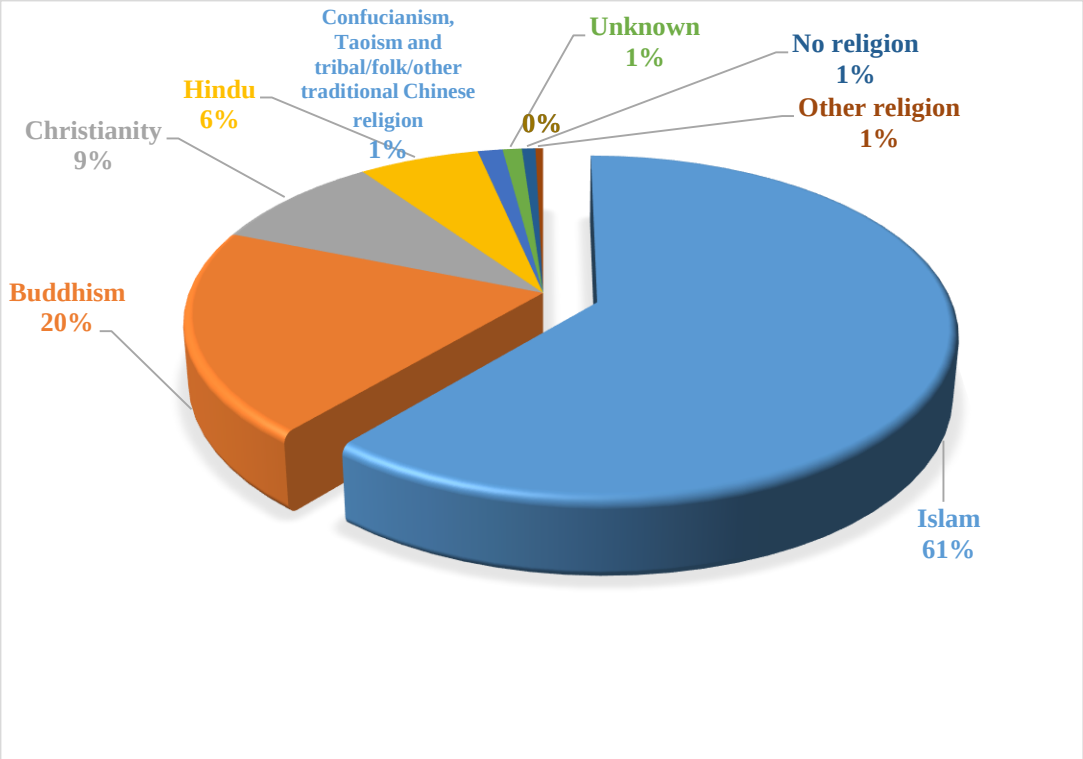

Figure 1.1: Pie chart shows the population of religions in Malaysia.
Source: (DepartmentofStatistics Malaysia, 2011)

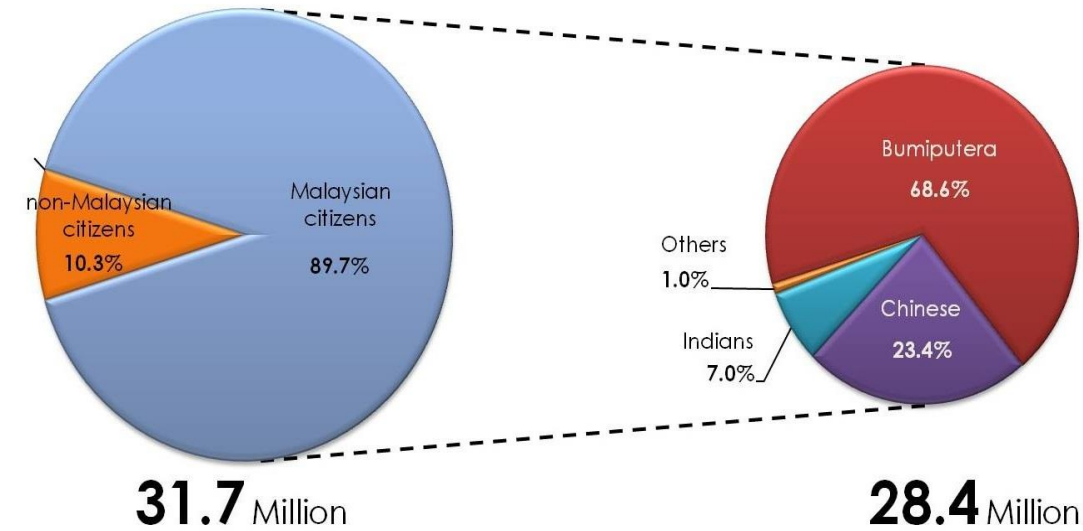

Figure 1.2: Percentage distribution of the population by ethnic groups, 2014-2016.
Source: (DepartmentofStatistics Malaysia, 2011)

According to the statistical pie chart above (figure 2), Muslim and Malay are the majority residents over other races or religions in Malaysia. Indirectly, it depicted that purchasing power in Malaysia comes from these group. However it is notable to observe that *ḥalāl* pharmaceutical has a promising yet long journey to develop understanding amongst pharmaceutical players itself in terms of *ḥalāl* and *ḥaram* substance, processes and methods (Tushar Saha et al., 2019). Although Malaysia is ranked as one of the top five Islamic leading economy ecosystem and contributed in pharmaceutical estimation which forecasted to reach at 131USD billion by 2023 (Shahar et al., 2019), there are plenty of efforts to be established and more rooms to improve on this matter.

Malaysia occupied the fourth ranking in highest purchasing power of Muslim population after Saudi Arabi, Turkey and Iran (Kearney, 2007). This phenomenon, certainly, pressured Muslim users into big strenuousness (*mashaqqah*) in daily life as many products and medicines available in market are not fully independent from such unlawful substances or methods of processing it. As the result, through the researcher's observation, consumerism space for Muslims in Malaysia will consistently linger in grey area (*shubhah*) if it is not properly managed.

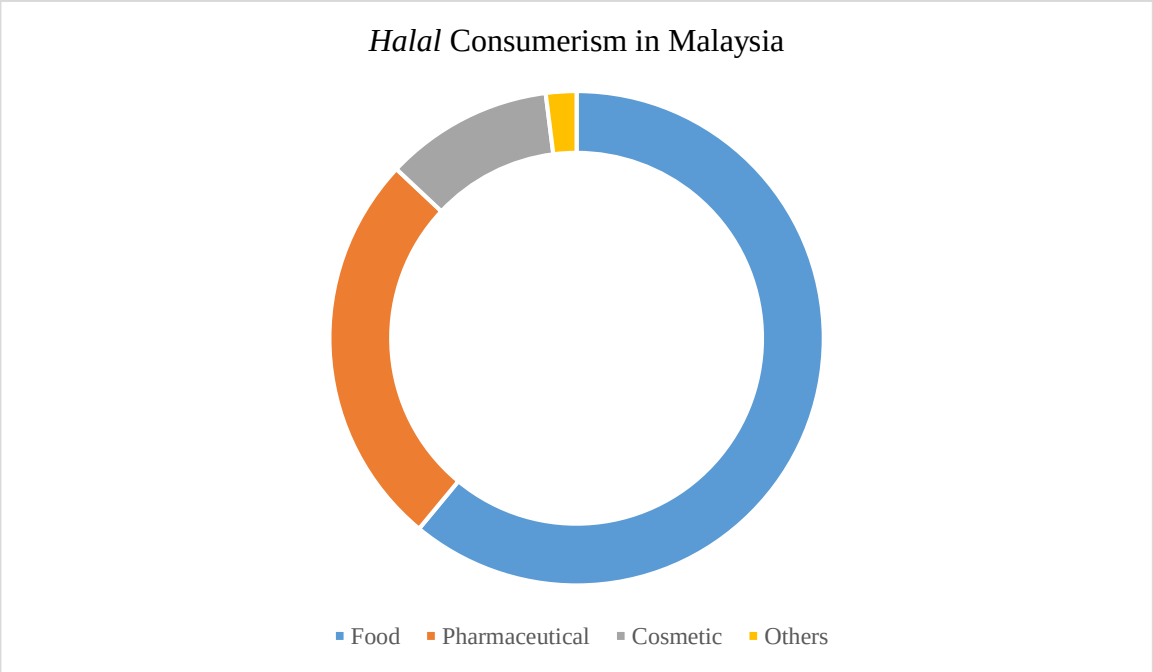

Figure 1.3: *Ḥalāl* consumerism in Malaysia. Source: *Ḥalāl* Product in Malaysia (HDC)

According to the pie chart above (Figure 1.3), *ḥalāl* concept has been gradually accepted especially in food industry followed by pharmaceutical industry at 26%. Yet; *ḥalāl* pharmaceutical awareness, has lower acknowledgement as compared to food industry Muslim population over the globe occupies almost quarter of the world (Ruzanna Muhammad, 2015) in current millennium and this offers a huge opportunity for *ḥalāl* pharmaceutical grow robustly. However, there are challenges that needs to be taken into account which include the origin of the sources, the processing and preparation method of the medicines shall be confirmed free from toxicity, pathogenic or forbidden items., If the vendor or host for the protein expression found contained those unlawful sources, then it will not be permissible for usage (Tushar Saha et al., 2019).

Without realizing, the majority population in Malaysia has strongly influenced the trend of consumerism in Malaysia which is mainly related to Islamic legal rules in consumerism. Furthermore, without meticulous comprehension in *fiqh* concept

pertaining to *ḥifẓ al-nafs* particularly *hifẓ al-ṣiḥḥah*, *ḥifẓ al-bīʾah* and *ḥifẓ min al-maraḍ al-khaṭīr*, it will definitely further complicate if the authorities either policy maker or scholars are approaching the Islamic legal rule way too rigid or too lenient.

Hence, this research has been carried out to explore the *fiqh* interpretation regarding preventive medicine using Low Molecular Weight Heparin (LMWH) which is porcine based anticoagulant for pregnancy and puerperium mothers whom are at risk of developing Venous Thromboembolism (VTE) in achieving and maintaining *hifẓ al-nafs* as mentioned earlier.

Therefore, this chapter presents the essential part of the research such as background of study, problem statement, research objectives, research questions limitations and significant of the research as follows;

1.2 Background of study

It is noteworthy to inform that Malaysia made a significant stride since Independence day in 1957-2010 owing to a systematic management of Confidential Enquiry Maternal Death in 1991 (Achanna et al., 2018). Apart from that, Malaysia ambitiously managed to achieve the reduction target of maternal mortality by three quarters between 1990 and 2015 as set in Millennium Development Goals (MDGs) set by United Nation in September 2000 (United Nations, 2015).

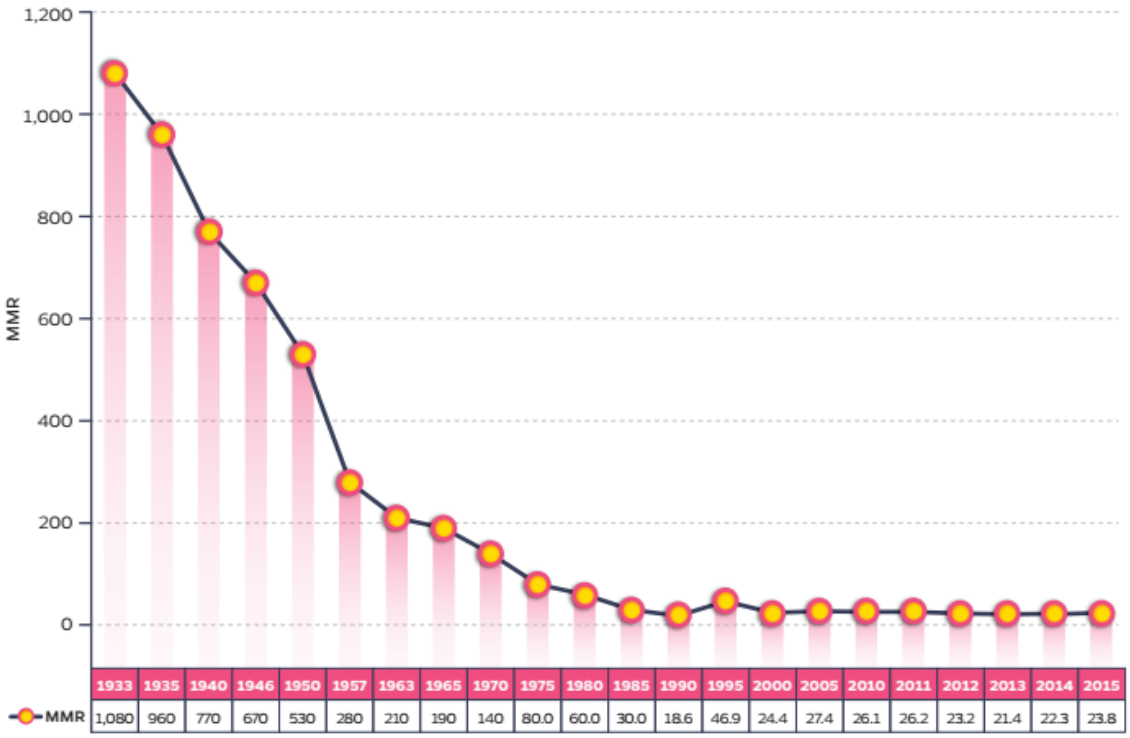

Figure 1.4: Maternal Mortality Ratio (MMR) in Malaysia: 1933-2015
Source: (DOSM, 2015)

The chart above displays the remarkable reduction of maternal death ratio from 1933 until 2015 according to department of statistic of Malaysia (DOSM). Figure 1.4 reveals that there has been a steep fall in five years prior to Independence Day year. Subsequently, displays a gradual decrease since 1957 until 1990 followed with slightly rise within five years afterward. It is clearly seen in this figure is the steady plateuing pattern of Maternal Mortality Ratio (MMR) statistic from year 2000 until 2015.

However, that plateau ratio of achievement is 23 per 100,000 LB from the target 11 per 100,000 LB in 2015 at the MDG level (Majdah, 2017). The latest reason causing unachieved target is VTE incidences which had been determined to be the top six causes of Malaysian maternal mortality in 2016 (Department of Statistic, 2017). Venous and air thromboembolism has become the principle cause of maternal mortality in Malaysia (figure 1.5).

The pregnancy itself is an unescapable risk for pregnant women to develop VTE with at least five-fold increment of risk (Unger, 2018) while women in the puerperium have 15 to 35 folds increased risk as compared to same age non-pregnant women (Bates et al., 2016).

Therefore, the researcher views that prevention measures such as prescribing a preventive medicine namely LMWH for prophylaxis purpose during pregnancy and puerperium has become a need to reduce maternal mortality and maintain women' well-being (Guimicheva et al., 2014) other than enhancing the health care system itself.

However, the controversial dilemma arises as it is a porcine base medicine and affects the Malaysian community by creating significant doubt with regard to the ingredient of LMWH and its usage. This is the largest factor causing a significant uproar upon women' refusal to take medicine (Irwan et al, 2018). Hence, a *fiqh* standpoint should be elaborated to guide all everyone including policy makers, healthcare providers, pharmaceutical experts, students, researchers and Muslim mothers in promulgating a decision which objectively preserving *hifẓ al-nafs*.

1.2.1 Maternal Mortality in Malaysia since 1957-2016/2017

Recent data of statistic of Malaysia in 2016 had gained citizen's attention when it was reported that obstetric embolism was the highest percentage and principal cause for maternal deaths (23%) followed by other causes of maternal mortalities including "childbirth and puerperium (18.2%), postpartum hemorrhage (11.5%), ectopic pregnancy (6.8%) and eclampsia (6.1%)" (Department of Statistic, 2017).

Even though there was significant decrement of maternal mortality from 44 per 100,000 LB in 1991 to 23 per 100,000LB (Department of Statistic, 2017) 1991-2015 (Yadav, 2014, A'isyah Sukaimi, 2018, Ravichandran & Ravindran, 2014, Hematram,

2006, Achanna, Krishnaswamy, Ponnampalam, & Bondhu, 2018) thromboembolism seems to be on top of the chart as the leading cause of maternal mortality (MOH, 2013).

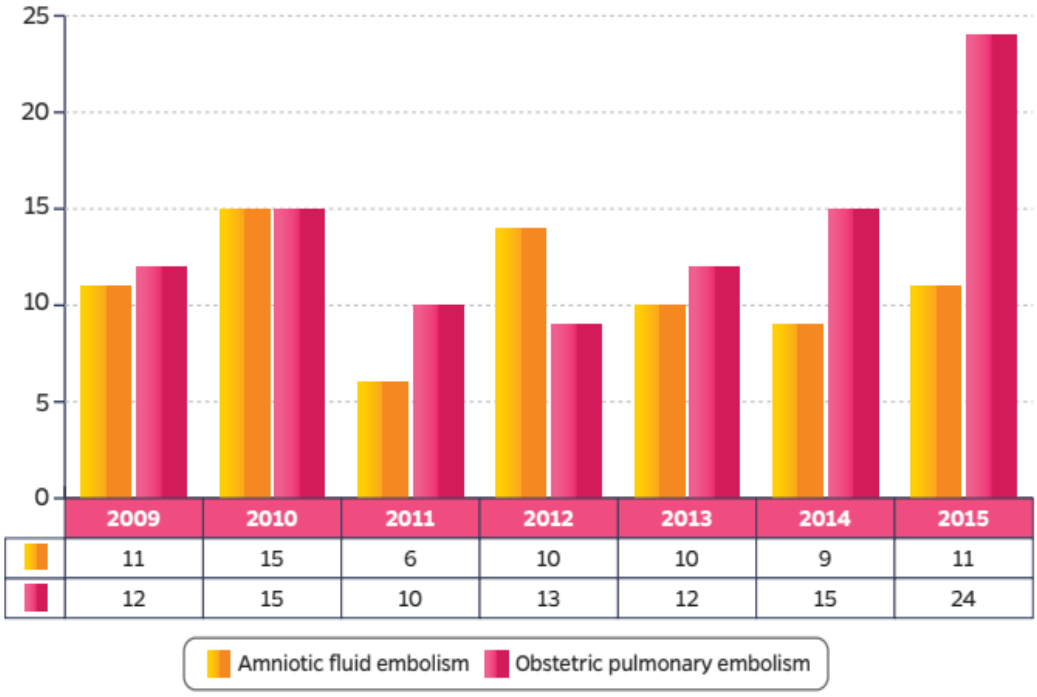

Figure 1.5: Number of maternal mortality due to obstetric embolism by type of Emboli, 2009-2015 Source: (DOSM, 2015)

The bar chart above (figure 1.5) shows that obstetric pulmonary embolism has been in alarming rise and threat upon Malaysian mothers in Malaysia witha steep rise within the three years from 2012 until 2015. As declared by UN- Secretary General, Ban Ki Moon' deploration on the slowest moving target of all MDGs (*Maternal and Newborn Health at 62nd WHA*, 2009), an aggressive effort shall be paid with regard that issue of safer motherhood particularly in terms of prevention and management of pulmonary embolism during pregnancy and puerperium.

Table 1.1: Maternal Mortality due to Obstetric Embolism: Malaysia from 2006-2015
Source: Report on Confidential Inquiries into Maternal Death in Malaysia: 2006-2011, Family Health Development Division: 2012-2015.

Type of emboli	2006	2007	2008	2009	2010	2012	2013	2014	2015
Pulmonary Embolism	9	7	23	12	15	10	13	15	24
Amniotic Fluid Embolism	9	17	17	11	6	9	10	9	11
Total	18	24	40	23	30	16	22	24	35

The table (1.1) above clearly displays that VTE either pulmonary embolism or amniotic fluid embolism attributable to 35 cases in year 2015 which indicates a crucial preventive measure should be undertaken as early as possible. PE is the most common case in VTE which accounted up to 6% of maternal death (MOH, 2013). Ministry of Health Malaysia hence has put in vigorous efforts in treatment and prevention of thromboembolism in pregnancy, including providing the most recommended medicine with the LMWH due to least negative effect, accessibility and cost effectiveness (MOH, 2014, Bates et al., 2016).

Table 1.2 Common causes of maternal mortality case in Malaysia
Source: 1997-2011: Reports on the Confidential Enquiry Maternal Death (CEMD) in Malaysia. 2012-2015: Family Health Development Division, MOH

CAUSES	1997-1999	2000-2002	2003-2005	2006-2008	2009-2011	2012-2014	2015
PPH	125	124	87	90	76	60	16
HDP	80	49	50	61	68	41	11
Amniotic fluid amniotic	50	43	40	43	32	28	11
Pulmonary embolism	18	37	39	39	37	41	24
Medical conditions	113	75	63	68	137	90	31
Puerperium Sepsis	14	18	9	9	15	8	0

Following these efforts, pulmonary embolism cases shows a decline from 41 cases to 24 cases compared to the years beforehand in 2015. In another hand, various effort from all sectors including medical researchers, academicians and analysis from shariah jurists should be hand in hand in order to reduce maternal mortality at the same time to save human lives. This is consistent with promotion on the well-being of the nations and regions in Islam' as general, the management and treatment of VTE to reduce maternal mortality is considered as crucial issue to be catered wisely.

1.2.2 Embolism is the Significant Cause of Maternal Mortality

Global Burden Diseases (GBD) study reported that thromboembolism is a major contributor to mortalities and morbidities of the world (ISTH Steering Committee for World Thrombosis Day, 2014). VTE is a leading cause of maternal mortalities and morbidities in developed countries worldwide (Ian A Greer, 2015) including England (Sultan, Tata, Grainge, et al., 2013), Scotland (Kane et al., 2013) and Australia (Australian Institute of Health and Welfare, 2017) which has shown that thrombosis has been the direct cause of maternal death.

Venous Thromboembolism (VTE) has two common presentation includes pulmonary embolism (PE) and deep vein thrombosis (DVT) (Bates et al., 2016). Confidential Enquiry Maternal Death (CEMD) of Malaysia reported in 2009-2014, state that there were 68 deaths caused by obstetric VTE in the period from 2012 to 2014, with 41 deaths (60.3%) due to blood clot embolism and 27 deaths (39.7%) due to amniotic fluid embolism (MOH, 2018).

It is notably that the increasing caesarean section rates is one of the known predisposing risk factor in this research because it could emerge as a risk factor of thrombosis (Karalasingam et al., 2020). Based on data published in 2010, women

delivered by caesarean section in Malaysia has gradually increased (Karalasingam, S. D., Jegasothy, R., Jeganathan, R., Zolkepali, A. & Aiman, 2012) while operative delivery have higher risk (Walsh & Malone, 2016)to be indicated as VTE risk itself without excluding other lifestyle factors such as obesity, age above 35 years, smoking and immobility (MOH, 2014).

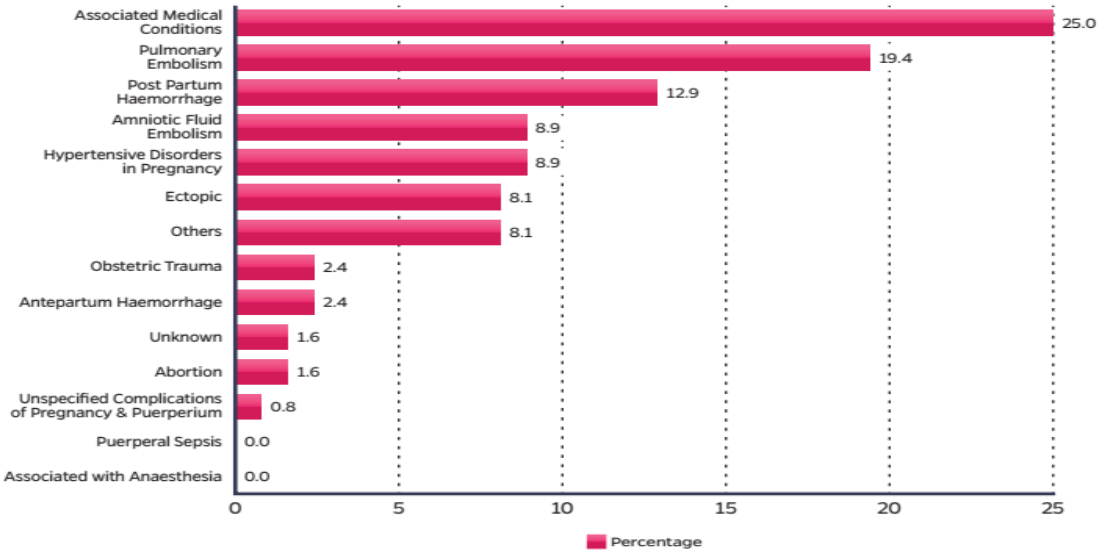

Figure 1.6: Causes of Maternal Deaths: Malaysia 2015
Source: (DOSM, 2015)

Table 1.3: The causes of maternal death: Malaysia 2015. Source: (DOSM, 2015)

CAUSES	2015
	n
Associated Medical Conditions	31
Pulmonary Embolism	24
Postpartum Haemorrhage	16
Amniotic Fluid Embolism	11
Hypertensive Disorders in Pregnancy	11
Ectopic	10
Others	10
Obstetric Trauma	3
Antepartum Haemorrhage	3
Unknown	2
Abortion	2
Unspecified complications of pregnancy & puerperium	1
Puerperal Sepsis	0
Associated with anaesthesia	0
Total	**124**

Figure 1.6 and table 1.3 indicated that pulmonary embolism is one of complications of VTE during pregnancy and puerperium which has been ranked as the second highest after associated medical conditions. This situation urges for role of thromboprophylaxis with pharmacological treatment since, caesarean delivery and obesity in Malaysia are unavoidable.

According to medical dictionary, a prophylaxis "is a measure taken to maintain health and prevent the spread of disease" while thromboprophylaxis means "any preventive measure or medication that reduces likelihood of the formation of blood clots" (Farlex et al, 2009). Thromboprophylaxis medications are made and used to reduce maternal morbidity and mortality. Its usage together with the efforts introduced such as providing training and awareness among the health care staffs, equipping them with the knowledge and better accessibility on the medicine are used to prevent VTE. It creates efficient and systematic method in dealing with thromboembolism (MOH, 2014).

The Ministry of Health (MOH) stated in the Training Manual of prevention and management of Thromboembolism during Pregnancy and Puerperium (MOH, 2018) that there are four choices of thromboprophylaxis agents for VTE treatment as following; LMWH, Unfractionated Heparin (UFH), Fondaparinux and Non-vitamin K Antagonist Oral Anti-Coagulants (NOACs). However, LMWH is recommended for thromboprophylaxis as prevention of Obstetric Thromboembolism in Malaysia (MOH, 2013) due to its bioavailability (Dado et al., 2019), safety and proven efficacy in over 1000 pregnancies (Rowan, McLintock, Taylor, & North, 2003, Lussana, Coppens, Cattaneo, & Middeldorp, 2012, Greer, 2015).

In response upon the ubiquitous implementation of LMWH as first choice in treating at-risk mothers of VTE, this research is established to extend the query of the

permissibility status of LMWH anticoagulant as preventive medicine which prescribed for pregnant and puerperium mothers by medical experts in order to preserve lives of mothers and babies from *fiqhi* point of view.

1.2.3 *Fatwā* on Clexane issued on 23rd-25th June 2009

Thromboprophylaxis by LMWH is preferred over types of anticoagulant by evidence as it is associated with a low incidence of complications (Ellison et al., 2000, Lepercq et al., 2001). Unfortunately, MCMKI on its 87th *muzakarah* between 23rd to25th June 2000, had issued a fatwa on prohibition in application of Enoxaparin Sodium (Clexane) and Fraxiparine with exceptional for patients with *ḍarūrah* state (JAKIM, 2015).

It is undeniable that Islamic medical jurisprudence has considered a room to execute the *ḍarūrah* legal ruling to treat a debilitating condition and prevent fatality using forbidden substances (Azri et al., 2017). However, VTE during pregnancy and puerperium are initially physiological changes in pregnancy in which later become complicated due to other associated risk factors (Alshawabkeh et al., 2016), yet, LMWH seemed as less favored option as it was overshadowed by MCMKI decision issued within years ago without any clause specifically explaining for usage in pregnancy and puerperium.

In another hand, a general statement mentioning another *ḥalāl* alternative, Fondaparinux (Arixtra) was advised instead of consuming Enoxaparin Sodium (Clexane) or Fraxiparine. The researcher has viewed that in the name of facilitation (*taysīr*) and flexibility (*murūnah*), which is a solution parallel with *fiqh* perspective and contemporary point of view should be pointed out to clarify between Islamic medical doctors and Islamic jurisprudence scholars in honoring this religion.

1.3 Problem statement

The significance of preventive medicine during pregnancy and puerperium in the domain of medical prevention regime is ostensive from the extensive initiatives in intensifying safe motherhood as prevention is better than cure (United Nations, 2015, Abdul Rashid & Sathar, 2013, MOH, 2018). As obstetric venous thromboembolism (VTE) is major leading cause of maternal mortality in developed countries, prevention and thromboprophylaxis is an amenable strategy to reduce maternal mortality (A. Friedman & Ananth, 2015). For example, In UK, the implementation of thromboprophylaxis regime as VTE preventive measures during pregnancy and puerperium reflected in the UK's maternal mortality reports in 2011, their maternal mortality report had marked the lowest rate ever since after thromboprophylaxis during pregnancy and puerperium was implemented (Walsh & Malone, 2016).

Although Malaysia made a significant stride since Independent day in 1957-2010 in the reduction of maternal mortality (Achanna et al., 2018), the latest ratio of achievement is 23 per 100,000 LB in 2015, we are still away from the Millennium Development Goals fifth target to achieve 11 cases per 100,000 LB with embolism reported as the principal death of maternal mortality in Malaysia (Department of Statistic, 2017). This situation leads to aggressive actions from the obstetricians to prevent VTE during pregnancy and puerperium, by implementing comprehensively thromboprophylaxis treatment with a medicine subcutaneously namely LMWH (Irwan et al., 2019).

GBD study reported that obstetric venous thrombosis is a major contributor to mortalities and morbidities of the world (ISTH Steering Committee for World Thrombosis Day, 2014). In the year 2016 (Department of Statistic, 2017) it revealed

that pulmonary embolism (PE) as principal cause of maternal mortality in Malaysia as referred to a retrospective study using maternal mortality surveillance data for the period of 2010-2015 (Sarah et al., 2017). It depicted there are two highest specific maternal mortality rate (MMR) factors. Firstly, advanced maternal age in pregnancy among 40-49 years old. Secondly, Malay ethnicity is the highest MMR in Malaysia whereby 75.3% maternal mortality occurred during postnatal phase. The most common risk factors of MMR which is implicitly related to this research such as caesarean section (58.4%), obesity (44.9%), parity more than three (40.4%) and age more than 35 years old (34.8%) are required thromboprophylaxis with Low Molecular Weight Heparin (LMWH) to reduce maternal mortality and morbidity in Malaysia nowadays. LMWH is opted in CPG provided by MOH as first anticoagulant that able to combat VTE as prophylaxis for the mothers who are at risk (MOH, 2013, MOH, 2018) and should obtain advise and supervision from obstetricians. This is merely because each patient profile and risk factors needs to stratified and would require different dose depending on their condition. For instance, pregnant women who have mechanical heart valve replacement have a very high risk to develop blood clot and require anticoagulant whole life, yet for these women the use of LMWH such as Clexane are safest in her pregnancy (Forte & Syringes, n.d.).

The Malaysian shariah scholars, MCMKI /JAKIM had released the decision in prescribing LMWH whereby it is allowed upon patients in *ḍarūrah* state as general (JAKIM, 2015). However, with the increasing risk factors and cases of VTE between dilemma among Muslim healthcare and patients has created misunderstanding and refusal of its usage despite guidelines and decisions released. Based on the situation, the researcher assumed that there is a vital gap in this situation with regard the conflict

understanding of *ḍarūrah* connotation accordance to *fiqh* perspective among medical healthcare providers with the jurists' terminology of *ḍarūrah* in LMWH issue.

Furthermore, MCMKI's decision regarding LMWH is inclusive all types of VTE either pregnant or non-pregnant condition as well as regardless any gender as it is a general decision without detail elaboration. At the meantime, MOH produced a detailed elaboration into types of VTE and pregnant and puerperium in the CPG and Manual Training 2018. Both clinical guidelines have stratified these pregnant women who are at risk of developing VTE into three categories such as high risk, moderate risk and low risk. A woman with moderate risk required to refer to specialist by 28 weeks of gestation antenatally and to be offered LMWH. Definitely, the high risk group is highly recommended to be treated with an effective anticoagulant yet been aversely accepted amongst Malaysian.

Literatures described that the main concern of prevention and treatment for VTE during pregnancy and puerperium is fatal risks associated to maternal mortality (Bates et al., 2016). There are several anti-coagulants which had been studied upon the usage for prevention and treatment of obstetric VTE cases; for example, vitamin K antagonist. Yet, it crosses the placenta and can cause teratogenicity, pregnancy loss, maternal bleeding and neurodevelopment deficits of the fetus while other agents such as dabigatran, rivaroxaban and apixaban, may also cross the placenta and should generally be avoided in pregnancy (Villani et al., 2017). Throughout years, thromboprophylaxis with LMWH has offered advantages over Unfractionated Heparin (UFH) and has been more ubiquitous all over the world including Malaysian hospitals because there are no documented data of maternal fatality or neonatal risk due to its use, a longer half-life, efficacy with once-daily dosing, and weight-based dosing (Alshawabkeh et al., 2016).

Thromboprophylaxis with LMWH as preventive medicine is pertinent to be applied for mothers so far due to the effectiveness of LMWH (Guimicheva et al., 2014, Goto, Yoshizato, Tatsumura, & Takashima, 2015) bioavailability (MOH, 2013), low cost (Subri, 2016, Sultan et al., 2013) and safety (Marshall, 2014) without denying that there is no ideal anticoagulant agent currently without at least lower side effects profiles (Alshawabkeh et al., 2016). This leads to the implementation of thromboprophylaxis with LMWH as prevention and management of VTE in training manual (MOH, 2018) and Clinical Practical Guideline for VTE prevention (MOH, 2013) as an established guideline for O&G departments in Malaysia which is applied by Malaysian Ministry of Health (MOH) since 2013.

However, despite recommended usage in various obstetric guidelines, LMWH has been observed as a sensitive issue in Malaysia because of porcine based origin and preparation. Researches on prevention of VTE with using LMWH which is extracted from mucosa layer of porcine intestine in the discipline of shariah are yet scarce at this moment in Malaysia.

Another gap that shall be need crucial attention is the ability of halal alternative of anticoagulant called Fondaparinux (Arixtra) in treatment of VTE either as prevention or therapy. Fondaparinux has been recommended to all kinds of VTE by MCMKI 2009 since it is verified as no avail of animal derivatives. Whilst CPG stated that Fondaparinux would be the last option for mothers who hyper allergy with heparin type of medicine (MOH, 2018) due to insufficient existing safety data (Unger, 2018).There was a non-published data of excretion of human milk (Bates et al., 2016) as well as less cost effective, non-easily affordable nor easily accessible (MOH, 2018). Yet, patients must be informed regarding its limitation of and current evidences.

Therefore, the effort to run an extensive research in tandem with *fiqh* view and providing succinct data regarding relevant anti-coagulant usage during pregnancy and puerperium proved that Malaysian Islamic body of authority is well aware with the need of current Islamic medical field.

Pregnancy and puerperium considered as highly potential risk of VTE sufferers. The Importance to determine the risk factors of obstetric VTE showed in literatures proves that the pregnancy itself is an unescapable risk for pregnant women to develop VTE at least five-folds (Unger, 2018, Conti, Zezza, Ralli, & Sada, 2013) as compare to non-pregnant women, with women in puerperium had 15-35 folds higher risk (Bates et al., 2016).

Pregnancy fulfills all three components of Virchow's triad: venous stasis, hypercoagulability and vessel wall damage, which are the known triggers for VTE (Guimicheva et al., 2014) although it is a physiological process for pregnant women. Normal pregnancy is associated with a hypercoagulable state characterized by increased concentrations of some pro-coagulant factors and simultaneous decrease of other anti-coagulant factors such as protein C and protein (Vineeta et al., n.d.).

This situation is threatening the pragmatic of *maqāṣid al-sharīʿah* in the name of preservation of lives (*ḥifẓ al-nafs*). In fact, in the case of VTE among pregnant women, it engages two lives; mother and baby. By ascertain that pregnancy alone is the big potential for mothers to have VTE, that situation is relevant to be stratified into *ḍarūrah* condition to be prescribed thromboprophylaxis with LMWH.

Based on these VTE risk factors surrounding pregnancy and puerperium, another ultimate issue here is how jurists and Muslim medical doctors are defining and determining the level of *ḍarūrah* among pregnant women and puerperium? What are the parameters for jurists and professional medical doctors to measure the fatality risk

and interprets its relation to *darurah* in this case? If the decision in 2009 which said LMWH (Clexane or Fraxiparine) is prohibited due to having *ḥalāl* alternative is the only reason, are we ready to put risk of unknown safety profile to both mother and unborn baby and it was not affordable or accessible to all patients. As a result, following the nonexistence of integrated parameter between shariah and medical fields, it probably creates an implicit standpoint of Islamic authority body which creates a deplorable state with regard the skeptical perspective regarding the implementation of thromboprophylaxis with LMWH (Clexane) in Malaysian government hospitals.

Perhaps it will not create a problem amongst shariah scholars in Malaysia because they do have capabilities to define and distinguish the scope of *ḍarūrah* itself. However, inharmonious situation occurs particularly amongst medical doctors who deal directly with the pregnant and puerperium women and pharmacists when prescribing LMWH to the patients who require it (Irwan et al., 2019, Dr. Jameelah Sattar, Dr Carol Lim Khar Koong, 2019).

Therefore, throughout this research, the researcher eventually had found out that thromboprophylaxis with LMWH shall be based on the principle of shariah in the usage of porcine base anticoagulant such as *ḍarūrah, ḥājah* and *istiḥālah*. However, since *istiḥālah* has no avail of MCMKI's enthusiasm as preference to Shafi'ite school of thoughts, the researcher analyzed that *qawāʿid fiqhiyyah* such as *al-ḍarūrah yuzāl*, *al-ḍarūrah tubīḥ al-maḥẓūrah* and *al-ḥājah tunazzal manzilah ḍarūrah* in partnership with *fiqh* discipline will be regarded as appropriate to be promulgated in this case.

1.4 Research Flow

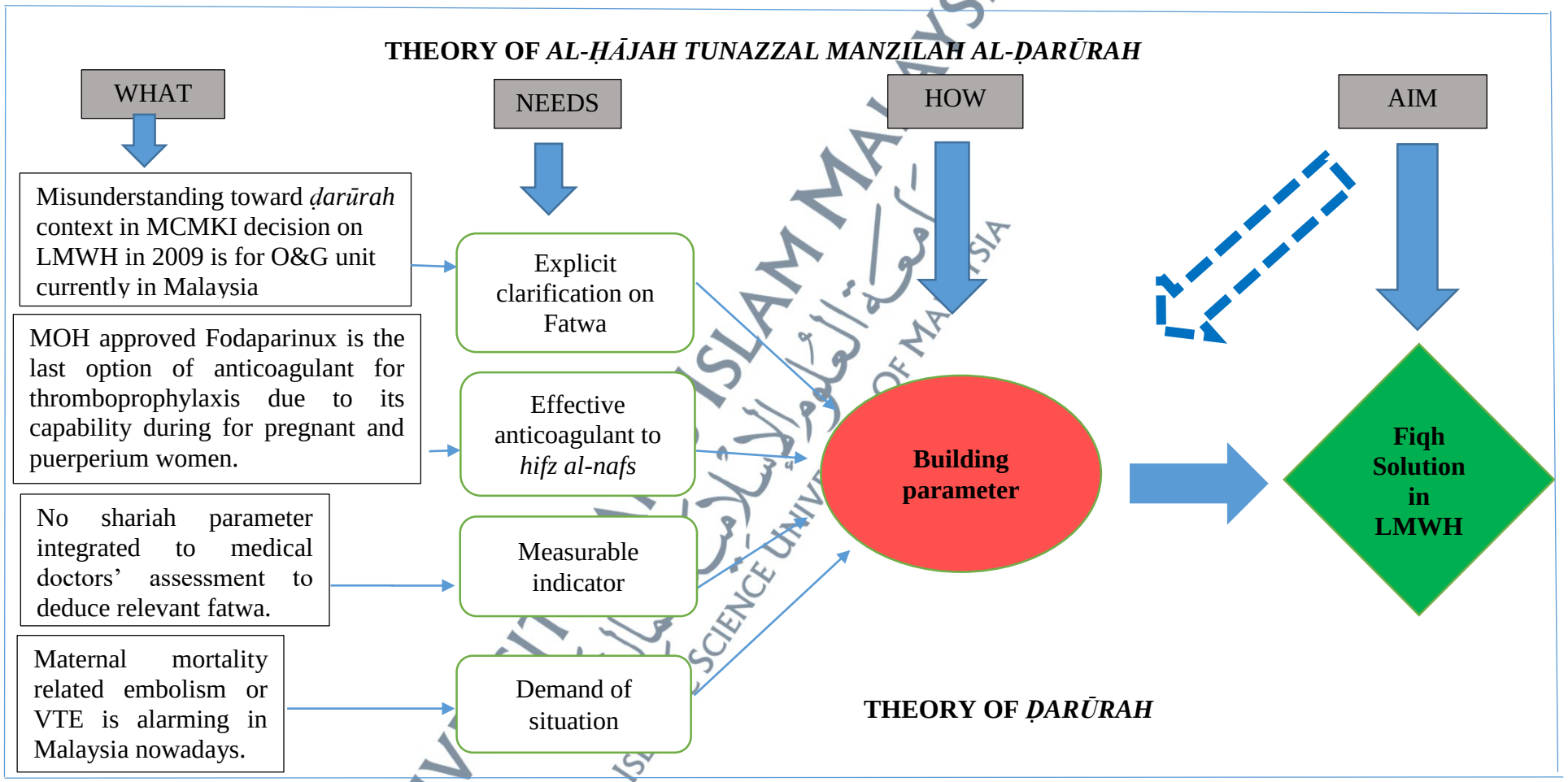

Figure 1.7: Concept mapping of the research

1.5 Conceptual Framework

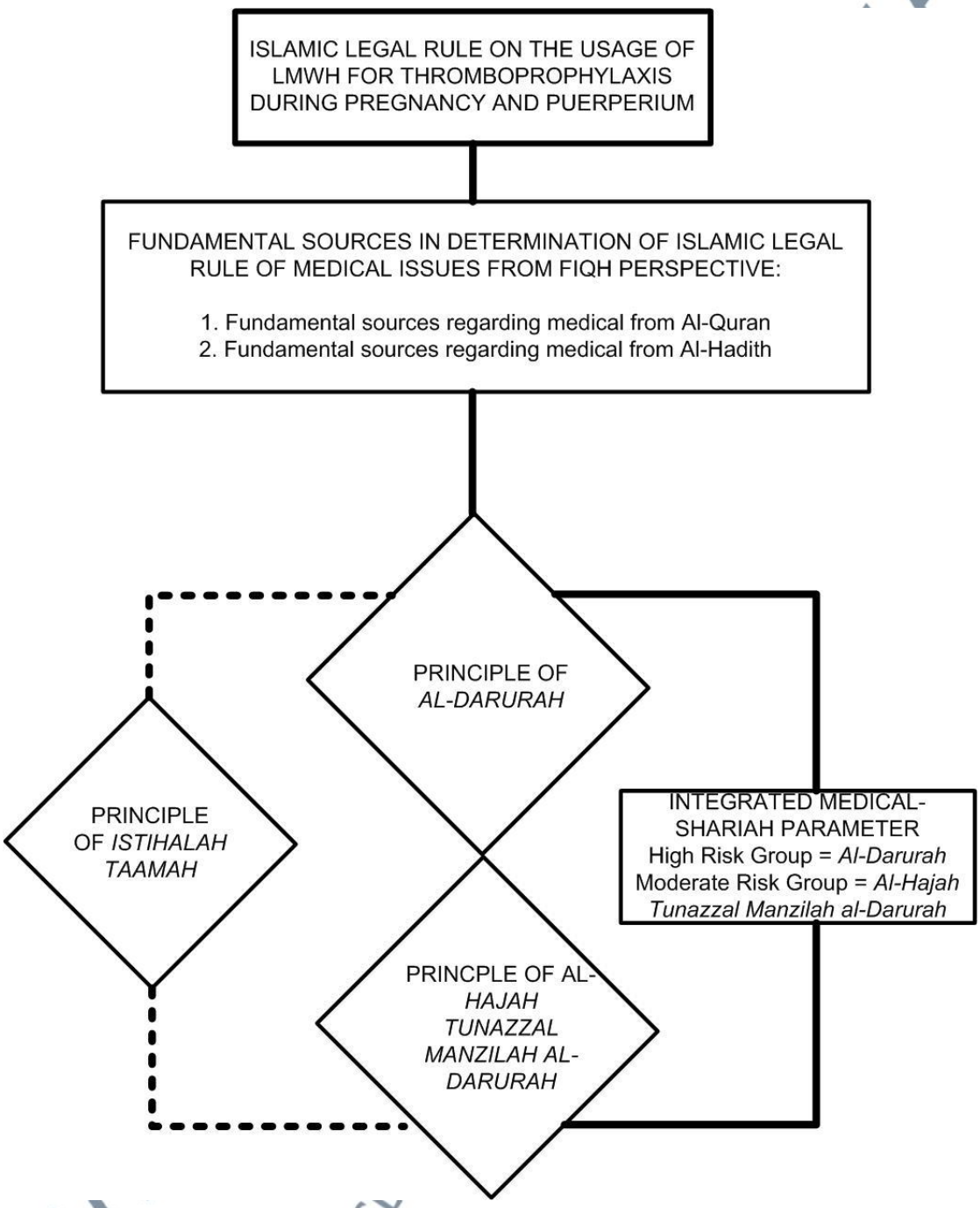

Figure 1.8: Conceptual Framework of this research

1.6 Research Questions

Referring to the problem statement and conceptual framework, three questions resulted for this research as following;

1. What is the prevention and treatment of VTE during pregnancy and puerperium?
2. How does principle of shariah deals with porcine based anticoagulant as a preventive medicine from *fiqh* perspective?
3. What is the recommended contemporary *ijtihād* from *fiqh* perspective regarding LMWH as preventive medicine upon pregnant women and puerperium to reduce maternal mortality in Malaysia?

1.7 Research Objectives

The research objectives are to answers the projected questions;

1) To elaborate the prevention and treatment of VTE during pregnancy and puerperium.
2) To analyze the principles of shariah in dealing with porcine based anticoagulant as a preventive medicine from *fiqh* perspective.
3) To recommend a contemporary *ijtihād* from *fiqh* perspective regarding LMWH as preventive medicine upon pregnant women and puerperium to reduce maternal mortality in Malaysia.

1.8 Significant of Study

This research will significantly affect some parties as following:

1. Saving human lives as stipulated in *maqāṣid al-sharīʿah* is always top priority overall as agreed by Muslim jurists. Mother's life will be taken care comprehensively in the name of human right, not merely the issue of sophisticated technologies.
2. Society will be clarified about the concept of *ḍarūrah* and the solution to eliminate the harms as well as the concept of *al-ḥājah* can alleviate the sufferings which can further lead to deteriorating of human lives simultaneously will vanish the *maqasid shari'ah*.
3. The concept of *istiḥālah* also can be a legitimate tool in deducing Islamic legal rule, in fact the treatment for it is seemingly urgent nowadays until a new drug being invented, which is free from porcine and has equivalent potential like LMWH.
4. Doctors in hospitals as the main players in this situation eventually will have peaceful mind in managing and treating their patient especially in O&G unit with regard to the case of VTE.
5. Contribute to the safer motherhood in Malaysia and reducing the maternal mortality and morbidity in concert to uphold the mission of MDG'5.
6. This research able to be an academic reference for researchers, academicians and students.

1.9 Research Limitation

The porcine base medicine is widely used in hospitals nowadays due to human's physiology and acceptance is very close to porcine. Apart from that, multi types of medicines had been extracted from porcine following scientifically proven. Porcine is included in the impermissible dietary constraint in Islam, even it is grouped under severe filth or *najāsah* in Islam. Due to some inabilities to cover all kinds of disorders which also need to be prescribed porcine based medicine, this research will only focus on some limitations as following:

First, porcine based medicine named LMWH as a case study. LMWH is grouped under a drug, also called as Enoxaparin Sodium, acting as anticoagulant of thromboembolism disorder. There are several types of LMWH that used in Malaysian Hospital such as Enoxaparin and Tinzaparin.

Secondly, the type of disorders that are treated by prophylaxis LMWH that chosen in this research is Venous Thromboembolism (VTE) during pregnancy and puerperium only. VTE is constituted by two commonest presentations, pulmonary embolism (PE) and deep venous thrombosis (DVT) although it can also present as other less common presentation in pregnancy such as ischaemic stroke or cavernous venous thrombosis. As saving lives is a top priority in *maqāṣid al-sharīʿah* after preservation of religion, some efforts must be strengthened to save mother's right to live in the best quality of life. Thus, management and treatment of VTE during pregnancy and puerperium should be intensified comprehensively.

Thirdly, in this research, *ḍarūrah* and *ḥājah* are fundamental theories that will be applied to the case study. The process of analyzing and assessing the extent to which women are positioned, either *ḍarūrah* and *ḥājah* as both theories will be parameters in deducing Islamic ruling in thromboembolism case. *Ḥājah* condition also is taken into account when viewed that LMWH for pregnancy and puerperium is better than unfractional heparin (UFH). LMWH will be critically examined either can be used in *ḥājah* condition or *al-ḥājah tunazzal manzilah al-ḍarūrah.*

Fourth, the theory of *istiḥālah* will be secondary theory in this research. Even though MCMKI does not recognize *istiḥālah* as valid parameter in the methodology of Shafi'ite sect in Malaysia of issuing any issues, yet, *istiḥālah* is not contradict toward shariah perspective. In fact, *istiḥālah* is a legal indicator in Islamic *fiqh* in other sects which associated with accurate (*saḥīḥ)* evidences from Al-Quran and Hadith.

1.9 Conclusion

In conclusion, the researcher observes that this shariah research deserves to be perpetuate academically in order to be part of the efforts to reduce maternal mortality which best translated into *hifẓ al-nafs* in Malaysia. Parties that will be affected positively from this research particularly authorities in Malaysia such as MCMKI, JAKIM and MOH. Thus, their directive supposedly able to be implemented in harmony besides cultivating a clear crystal understanding about *ḍarūrah* concept in shariah amongst the frontliners such as medical doctors, pharmacists and shariah scholars in Malaysia. A research focused on the conflict issue must be carried out to halt misconception amongst community especially Muslim consumers since it involved with unlawful substance in medicinal substances.