



**FREQUENTLY ASKED
QUESTIONS
ON
VACCINES AND
IMMUNISATION**

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Frequently Asked Questions on Vaccines & Immunisation

1. What is a vaccine?

A vaccine contains antigen(s) that is formulated using parts or whole of virus or bacteria, either killed or inactivated (weakened). It is used to induce our body's immune system to develop protective immunity against specific diseases.

Today, most vaccines are in combinations to ease the administration process. Combination vaccines are multiple vaccines combined into a single injection so that children get protection from multiple diseases in one shot, hence making administration less painful and more convenient.

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2. What does vaccine contain?

Vaccines contain an active ingredient, the antigen. Depending on their purpose and specific composition, vaccines can contain live viruses, killed viruses, purified viral proteins, inactivated bacterial toxins or parts of the bacteria. They also contain additional components such as preservatives, stabilisers, adjuvants and traces of other components. Each ingredient used in vaccines has a specific function and contributes to the quality, safety and efficacy of the product. Vaccines do not contain ingredients that will harm the body.

Preservatives are used in some vaccines for vaccine stability and also for prevention of bacterial and fungal growth. Commonly used preservative is thiomersal (or thimerosal). It contains a form of mercury called ethyl mercury which is not associated with any of the toxic effects of methyl mercury, a known neurotoxin. Thiomersal has been used in vaccines in very small amounts for about 80 years, with no evidence of it being harmful.

Upon review of the current epidemiological evidence and pharmacokinetic profile of thiomersal, the WHO Global Advisory Committee on Vaccine Safety concluded that there is currently no evidence of mercury toxicity in infants, children or adults exposed to thiomersal in vaccines. In addition many well-conducted studies and reviews by expert panels have shown that there is no evidence of developmental or neurologic abnormalities, such as autism, resulted from the use of vaccines containing thiomersal.

Stabilisers prevent the vaccine components adhering to the side of the vaccine vial. It maintains the vaccine's safety and effectiveness under different conditions and temperatures. Gelatin and lactose-sorbitol are examples of stabilisers.

Adjuvants are added to some vaccines to enhance the immune response to the vaccine. Most commonly used adjuvant is aluminium salts (known as alum). Aluminium intake from vaccines is lower than everyday intake from diet or medications such as antacids. A review of all available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination) found that there was no evidence that aluminium salts in vaccines cause any serious or long-term adverse events. Redness and swelling at the injection site is commonly associated with aluminium-containing vaccines compared to those not containing aluminium, but this side effect is usually mild.

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3. Are some vaccines made using fetal cells?

Fetal cells are used to make five vaccines: Rubella, chicken pox, hepatitis A, shingles and rabies. It is used to grow these viruses for vaccine manufacturing. Fetal cells were isolated from two elective abortions performed in Sweden and England in the early 1960s.

Further abortions are not necessary as the cells isolated in the 1960s continue to be maintained in laboratory cultures. There are several reasons why scientists choose to use fetal cells:

- i. Viruses, unlike bacteria, require cells to grow, and human cells are often better than animal cells at supporting the growth of human viruses.
- ii. Fetal cells are different from other type of cells in that they are virtually immortal, meaning they can reproduce many times before dying. Other cells reproduce only a limited number of times before they die.

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4. Why is formaldehyde in vaccines?

Formaldehyde is a by-product of vaccine production. Formaldehyde is used during the manufacture of some vaccines to inactivate viruses (like polio and hepatitis A viruses) or bacterial toxins (like diphtheria and tetanus toxins). While most formaldehyde is purified away, small quantities remain.

Formaldehyde is also a by-product of protein and DNA synthesis, so it is commonly found in the blood stream. The quantity of formaldehyde found in blood is ten times greater than that found in any vaccine.

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5. Why is antibiotic in vaccines?

Antibiotics are used to prevent bacterial contamination during production of some vaccines. There are concerns that antibiotics in vaccines may be harmful on the basis that, sometimes when antibiotics are given to people to treat infections, they can cause systemic allergic reactions. However the type of antibiotics used in vaccines such as neomycin, streptomycin, polymyxin B, chlortetracycline, amphotericin B are not those to which people are usually allergic.

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6. Manufacturing process of vaccines

The manufacture of vaccines is achieved from the propagation of living organisms. Some of these may be dangerous human pathogens. Therefore, the manufacture of vaccines is conducted in a highly regulated and controlled environment. All vaccine manufacturers are subject to national and international regulatory control and must comply with specifications for Good Manufacturing Practices (GMP). The fundamentals include:

- to ensure that products are safe for use in humans; and
- to ensure that the identity, strength, quality and purity of products consistently meet regulatory specifications.

Manufacturing is conducted in an aseptic environment and closely monitored by quality control measures. The actual production processes might vary for different types of vaccines as some components of the manufacturing process are specific to either viral or bacterial vaccine production. In general, the production of vaccines entails four basic steps (See Figure 1).

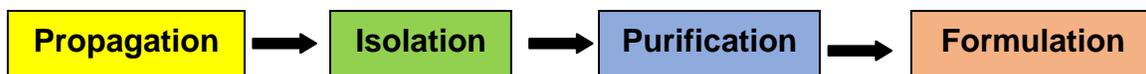


Figure 1 : The four steps in the production of vaccines

i) Propagation

Multiplication (or amplification) of the living organism used in the vaccine.

ii) **Isolation**

Separation of the living organism from the cells or growth media used in the propagation step.

iii) **Purification**

Removes all materials that may be adhering to the isolated organisms or selectively separates the portion of the living organism to be used in the vaccine.

iv) **Formulation**

Involves the mixing of the purified product in solutions to obtain a desired concentration. It may also include the addition of components such as preservatives, diluents, adjuvants and stabilisers. At the end of the manufacturing process, vaccines are typically filled in vials or syringes and packaged for shipping to healthcare providers.

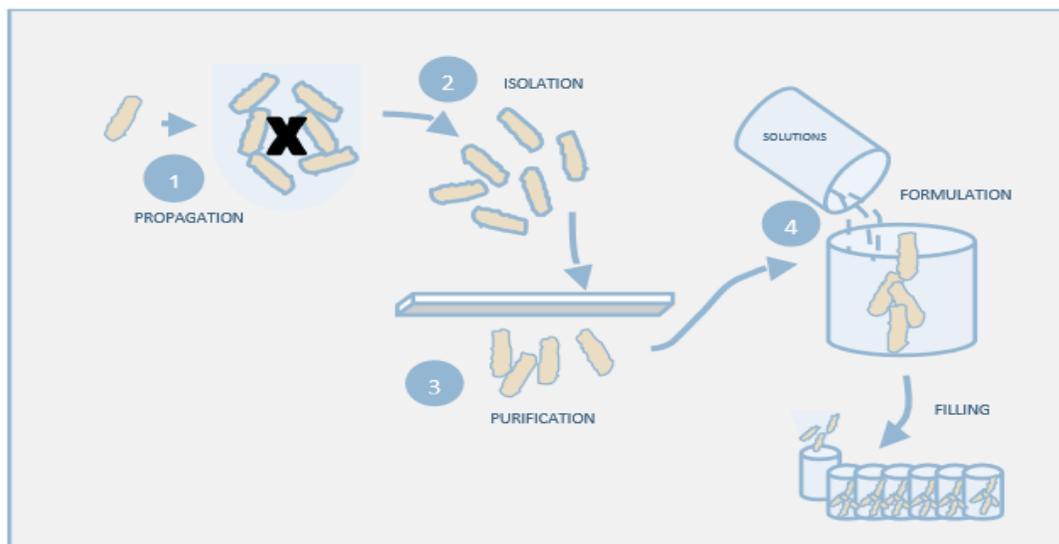


Figure 2 : Processes involved at each of the four steps of vaccine manufacturing

Source : Vaccine Fact Book 2012, page 58

e.g. Manufacturing Process of Viral Vaccine

As viruses only grow within living cells, viruses for vaccines are propagated in cells (e.g. in chicken eggs) or in continuous cell lines (e.g. Vero cells). Once the virus has been propagated, it must then be isolated from the cells and the cell-culture medium. This may be achieved by several techniques including chemical lyses of the cell, centrifugation and filtration or homogenization.

The next step, purifying the virus, may likewise involve multiple techniques of centrifugation, ultra-filtration, chromatography or chemical purification. At this stage, viruses may also be chemically inactivated for killed vaccine preparations.

Then the viral preparation is formulated by mixing it with the constituents that allow each dose to be safely delivered in the right concentration. This is the point where the product may also be combined with other antigens (e.g. measles–mumps-rubella vaccine). The formulated product is filled in vials or syringes. Some vaccines are freeze-dried (lyophilized) at this stage, to prolong their shelf-life.

e.g. Manufacturing Process of Bacterial Vaccine

Bacteria do not require living cells to propagate and are instead grown in bioreactors containing specific culture media. After propagation, isolation may be conducted by centrifugation or specific polysaccharide extraction techniques. Purification is specific to the antigen, but may include chemical precipitation or fractionation, or ultra filtration and chromatography steps. At this stage, carrier proteins may be conjugated to some polysaccharide vaccines and the conjugate vaccine is then purified by various filtration or chromatography techniques. The purified products are then formulated and at this stage may be combined with several other antigens. Some polysaccharide vaccines contain several types of polysaccharide (e.g. pneumococcal polysaccharide vaccine contains 23 different types of polysaccharide), and some bacterial vaccines are combined with other bacterial and / or viral antigens (e.g. diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b (Hib)-Hepatitis B or DTP-Hib-Hep B).

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7. How vaccine works

Your child's body naturally produces cells and antibodies to help protect against viruses and bacteria. However, these defense mechanisms can be stimulated when a vaccine is administered into the body. The antigens in vaccines act to stimulate the immune system to produce antibodies against specific diseases, thus strengthening immunity by priming the defense cells to recognize the particular virus or bacteria so that they can better fight it in the future. The maximum effect of the vaccine will usually only take place ('kick start') after the last dose in the schedule has been administered.

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8. Why immunise children at a young age?

Children are most vulnerable to vaccine-preventable diseases due to their weaker immune system. Vaccines help strengthen their immune system and protect them from potentially life-threatening complications. Hence, it is highly recommended that children are vaccinated as early as possible according to the immunisation schedule.

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9. Do vaccines really prevent diseases?

Through vaccination;

- Smallpox was successfully eradicated from the world in 1980. Smallpox was an untreatable disease with high case fatality rate, cause scarring or blindness to the survivors.
- Poliomyelitis was eradicated in three (3) World Health Organisation (WHO) regions i.e. America, Europe and Western Pacific Region (WPR). Malaysia achieved the eradication status in October 2000.
- Morbidity and mortality for many vaccine preventable diseases have been significantly reduced. Immunisation makes the world a safer place by saving millions of lives from diseases which are preventable. Without immunisation, 2 to 3 million more children and adults would die every year from poliomyelitis, meningitis, diphtheria and many other vaccine-preventable diseases (VPD).
- We are protected from certain cancers i.e Human papilloma virus vaccine and hepatitis B vaccine protect against cervical cancer and liver cancer respectively.

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10. My child is healthy and strong. Why does he/she need to be immunised?

There is no guarantee that a healthy child will always be free from infection of vaccine-preventable diseases. The disease can strike when we least expect them. If a child is vaccinated, he/she will be protected from these diseases.

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11. Does vaccine confer 100% protection against vaccine preventable diseases?

Vaccines may not be 100% effective. Different people respond differently to vaccines, and it is possible that some people may not generate an adequate immune response to the vaccine. As a result, these individuals may not be effectively protected. There are some vaccines that need additional or booster doses to help raise immunity against specific disease. The protection offered by vaccines is better than no protection at all.

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12. Isn't natural immunity better than vaccination?

In order to develop natural immunity to a specific disease, a child needs to be infected by the bacteria/virus, and to completely recover from the disease first. This will put the child at risk of potentially life-threatening complications. Vaccines, with killed or weakened (inactivated) bacteria/virus offer protection that is as good as that of natural immunity, without putting your child through such risk.

Vaccine uses a person's natural response to disease to stimulate the immune system so that if someone is exposed to the specific pathogen in the future their immune system can "remember it" and mount an effective response to either stop the disease from developing or reduce the severity of the disease.

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13. How long will the protection of a vaccine last?

Different vaccines provide protection for varying amounts of time. This is a result of the different ways vaccines are made. Certain vaccines may confer lifelong immunity. Other vaccines can protect up to 30 years. There are a handful of vaccines that require boosters for continued protection.

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14. Why are some vaccines given many times?

Some vaccines confer immunity only for a certain period. Therefore booster shots are required to restimulate the immune system. If your children don't get their boosters on time, they may no longer be protected.

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15. Timing of vaccination is important

Different vaccines are given at varying intervals in order to safely give the body the reminder it needs to build appropriate immunity. The interval between each immunisation depends on the properties of each specific vaccine.

Follow the schedule accordingly to ensure your children receive all the dosages to get optimum protection.

If your child misses a dose, inform your doctor/ nurses immediately. A new date will be advised, to continue with the subsequent doses.

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16. Vaccines protect not just us, but others in the community (herd immunity)

When a significantly large proportion of the community has protective immunity against a certain vaccine preventable disease, the bacteria/virus can hardly find a susceptible person in the community to infect. The whole community is therefore protected against the disease, which is known as herd immunity. The presence of herd immunity conferred by high vaccination coverage will protect this susceptible group from getting an infection. Immunisation does not just protect the individual but entire families, communities and countries too. As a member of the community, we have the responsibility to protect those who are not suitable to be immunised but are at high risk of getting an infection (immunosuppressed), such as children who have cancer and have to undergo chemotherapy.

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17. How can vaccine be safe if they are made from germs?

Vaccines are developed from whole or parts of virus or bacteria that have been killed or weakened. They are not able to cause disease in healthy children.

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18. There seems to be too many childhood vaccines, won't my child's immune system be overwhelmed?

Vaccines will not overwhelm a child's immune system as the immune system is able to respond to multiple changes. Vaccines contain a much smaller number of antigens as compared to foreign antigens exposed through eating, drinking and other activities. Hence multiple vaccines given concurrently or within a short interval will not harm your children's immune system.

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19. Are vaccines safe, especially for babies and very young children?

Before vaccines are marketed commercially for use, they are rigorously tested in thousands of people in progressively larger clinical trials which are strictly monitored for safety. The Drug Control Authority, Ministry of Health Malaysia must register/approve a vaccine before it can be used and introduced in the immunisation programme in Malaysia.

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20. Do vaccines cause side effects?

Vaccines may produce some undesirable side effects, such as pain and redness at the injection site or fever, but most reactions are mild and resolve quickly. It is usually not possible to predict who may have a mild reaction and who may have a rarer, serious reaction to a vaccine.

Ministry of Health Malaysia continuously monitors the safety of vaccines. Healthcare personnel from government and private healthcare facilities, vaccine companies and the public can report any side effects or adverse events experienced after receiving a vaccination to the ministry by contacting 03 - 7883 5400 or send an email to: bpfk@bpfk.gov.my.

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21. Are there any reasons why someone should not be immunised?

Always discuss with your doctor / nurse before your child receives a vaccine. Inform your doctor / nurse any family's medical history and pre-existing medical conditions or allergies your child might have. It will help to determine whether your child should not receive specific vaccines.

The following individuals are advised to talk to doctor / nurse before receiving vaccination:

- Experienced a serious reaction to a previous dose of a vaccine.
- Have pre-existing medical conditions such as cancer, HIV/AIDS, diabetes, heart or lung diseases and others.
- Receiving treatment for cancer, steroid-therapy or immunosuppressant, as this weakens the immune system.
- Pregnancy as certain live vaccines is not recommended during pregnancy.
- If feeling unwell on the day of vaccination especially with moderate to severe symptoms.

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22. Why Adults Need To Be Immunised

Pregnancy

Many diseases can affect both the pregnant woman and her unborn baby. Examples include hepatitis B, rubella, tetanus and so on. There are vaccines that you can receive before you conceive which will prevent many complications for both you and your child.

Travelling

Some diseases are endemic in certain parts of the world. This is why specific vaccines are recommended (e.g. yellow fever before visiting countries with risk for yellow fever virus transmission e.g. certain African countries). For example, a person needs to be vaccinated against polio before travelling to Nigeria, Afghanistan or Pakistan, as these countries still have active poliomyelitis cases. Muslim pilgrims going for Haj are also required to take meningococcal vaccine as regulated by the Government of Saudi Arabia. Regardless of such regulations, it is always a good idea to be vaccinated when travelling. This is to prevent from being infected overseas and bringing it home to loved ones.

Seasonal Illnesses

Vaccines offer protection from seasonal diseases, like influenza which happens every year. These vaccines can prevent absenteeism, hospitalisation or death when outbreaks occur. Older adults and individuals with weak immune systems or chronic health conditions are at higher risk of developing complications and should therefore consider seasonal immunisation.

Older adults

Older adults (above 65) generally have weaker immune systems, and hence are more susceptible to vaccine-preventable diseases. They are, therefore, advised to get certain vaccines such as the pneumococcal vaccine.

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23. Vaccination Refusal among Groups Practicing Homeopathy

There is no scientific basis to support the use of any homeopathic preparation in preventing diseases targeted by conventional vaccines. The effectiveness of conventional vaccines is well established through large-scale studies of their safety and efficacy. There have been very few studies where homeopathic preparations have been subjected to any scientific scrutiny. None of these studies have been on a preparation for use against a disease on the current national immunisation schedule. Therefore, the efficacy of homeopathic preparations against these diseases has not been established.

Several homeopathic substances marketed as 'vaccines' are available. Most of these preparations are manufactured by making successive dilutions of disease, tissue or plant extracts, to the point where none of the original material is contained within the preparation. This process of 'succussion' is said to transfer the protective activity of the original material to the diluting water. However, there is no biologically plausible

mechanism for how the ingestion of homeopathic preparations could prevent infections and/or their related diseases.

Many homeopathic practitioners support conventional vaccination to protect against vaccine-preventable diseases. The Australian Homeopathic Association and the United Kingdom Medical Association for Homeopathy recommend conventional vaccination with standard vaccines. The Society of Homeopaths in the United Kingdom does not encourage its members to advise patients against vaccination.

The President of Majlis Perubatan Homeopathy Malaysia (MPHM), Mr Zainul Azmi b. Ahmad also has the same view with other international homeopathy bodies such as British Homeopathic Association, Faculty of Homeopathy London, European Committee for Homeopathy, European Central Committee for Homeopathy, International Council For Homeopathy and Australia Register of Homeopaths on immunization. Immunisation should be given using the recommended vaccines.

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24. The National Immunisation Programme

The Malaysian National Immunisation Programme was introduced in early 1950s. The services is provided free to protect children from the infection of tuberculosis, hepatitis B, diphtheria, pertussis, tetanus, poliomyelitis, *Haemophilus influenza* type b, measles, mumps, rubella, human papillomavirus and Japanese encephalitis .

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25. Roles of Health Care Workers

- Always explain to your patients or parents before vaccination is given, on the benefits of vaccination and the importance of adhering to the immunisation schedule.
- Inform them regarding which vaccine is going to be administered.
- Briefly explain on the side effects or adverse effect that he/she might experience.
- Administer the injection as prescribed
- Write the name of vaccine, batch number and the expiry date on the children's health card.

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26. Apa Pandangan Islam Mengenai Penjagaan Kesihatan Ummah

Di dalam Islam penjagaan terhadap lima (5) perkara utama yang terkandung dalam Maqasid Syar'iyah iaitu **agama, nyawa, akal, keturunan dan harta** adalah amat dituntut. Penjagaan dan pemeliharaan syariat terhadap lima (5) kriteria asas tersebut merupakan satu perkara yang sangat penting dalam penentuan Syariat Islam.

Kesihatan individu dan masyarakat adalah antara tuntutan agama dan kehidupan, di mana ia akan memberi manfaat dan kemaslahatan kepada kehidupan seluruh umat manusia. Oleh itu, tindakan pencegahan daripada perkara-perkara yang boleh memudharatkan kesihatan dan nyawa manusia adalah amat dituntut oleh Islam bersesuaian dengan kaedah Fiqhiyyah **سد الذرية** (Menyekat Pintu Kerosakan)

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27. Adakah Islam Membenarkan Imunisasi

Imunisasi adalah satu cara pencegahan yang dapat dilakukan bagi mengelakkan penyakit-penyakit merbahaya yang mengancam nyawa, khususnya kanak-kanak seperti demam campak (measles), tibi (batuk kering), batuk kokol (pertussis), difteria, tetanus (kancing gigi) atau polio. Penggunaan vaksin dalam program imunisasi bagi mengelak bahaya penyakit-penyakit yang berkenaan adalah diharuskan oleh syarak selaras dengan Kaedah Fiqhiyyah iaitu **مدقم دسافل اورد** (جلب المصالح) menolak kerosakan adalah didahulukan daripada mencari kemaslahatan).

Sesuatu kerosakan akan cepat berkembang dan bahayanya adalah lebih besar sekiranya tidak dicegah daripada awal. Keharusan ini juga adalah berdasarkan Firman Allah s.w.t dalam surah Al- Baqarah, ayat 195 yang bermaksud: Dan janganlah kamu sengaja mencampakkan diri kamu ke dalam bahaya kebinasaan.

Program imunisasi ini bukan lagi merupakan kehendak seorang individu, tetapi imunisasi kini menjadi keperluan kepada masyarakat secara umumnya.

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28. Adakah Islam Membenarkan Penggunaan Ubat Daripada Sumber Yang Haram

Islam pada dasarnya menegah penggunaan ubat dari sumber yang haram untuk mengubati sesuatu penyakit. Ketetapan ini adalah berdasarkan hadith Rasulullah s.a.w. yang bermaksud: “Dari Abi Darda’ RA, Rasulullah s.a.w. berkata: Sesungguhnya Allah telah menurunkan penyakit dan penawar, dan Dia telah menjadikan bagi tiap-tiap penyakit itu penawar, maka kamu semua berubatlah dan janganlah kamu semua berubat dengan (perkara-perkara) yang haram”.

Walau bagaimanapun, dalam **keadaan darurat** di mana tiada ubat lain yang boleh digunakan secara berkesan untuk mengubati sesuatu penyakit, sedangkan sesuatu penyakit itu perlu dicegah dan dirawat untuk memelihara kesihatan diri dan nyawa, ubat yang bersumberkan perkara-perkara yang ditegah adalah diharuskan selama mana tiada ubat lain dari sumber yang halal ditemui dan ianya dilakukan mengikut kadar yang diperlukan sahaja.

Dalam mempertimbangkan keharusan ini, syarat-syarat yang ditetapkan untuk memastikan keperluan tersebut berada di peringkat darurat perlulah dipenuhi. Syarat-syarat tersebut ialah:

- a. Berlaku atau wujud satu keadaan di mana kemusnahan atau kemudharatan pada lima perkara asas ataupun kemusnahan akan berlaku secara pasti ataupun berdasarkan kepada sangkaan yang kuat berpandukan pengalaman-pengalaman atau pengetahuan;
- b. Seseorang yang berada dalam keadaan darurat itu bertentangan dengan perintah atau larangan syarak, atau tidak terdapat sesuatu yang diharuskan oleh syarak untuk menghilangkan kemudharatan melainkan perkara yang ditegah;
- c. Mestilah dipastikan bahawa kewujudan benda-benda halal yang lain tidak dapat menghindarkan kemudharatan yang menimpa pesakit;
- d. Pengambilan yang haram itu sekadar keperluan sahaja; dan
- e. Pada waktu pengubatan, pengambilan yang haram itu hendaklah dipasti dan perakui oleh seorang doktor pakar muslim yang adil.

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29. Apa Pendirian/Ketetapan Jawatankuasa Fatwa Majlis Kebangsaan Bagi Hal Ehwal Ugama Islam Malaysia Mengenai Imunisasi

Fenomema ibubapa enggan memberikan suntikan imunisasi kepada anak-anak mereka di klinik-klinik adalah amat membimbangkan. Perbuatan ini bukan sahaja merbahaya kepada anak-anak yang merupakan generasi masa depan kita, tetapi juga boleh menjadi punca merebaknya jangkitan penyakit-penyakit merbahaya tersebut.

Dalam hal ini Islam amat menitikberatkan keselamatan umat manusia. Perlu difahami bahawa sesuatu perkara yang hendak dilaksanakan untuk masalah ummah hanya diperakukan oleh syarak sekiranya tidak bercanggah dengan Maqasid Syar'iyah iaitu menjaga agama, nyawa, aqal, keturunan dan harta. Menurut fuqaha', sebarang penyakit perlu dihindari, dirawat dan diubati. Dalam konteks ini pencegahan daripada sebarang bentuk gejala yang boleh menjejaskan kesihatan dan nyawa adalah menjadi pegangan dan keutamaan ajaran Islam.

Berdasarkan ketetapan dan panduan syarak tersebut, Muzakarah Jawatankuasa Fatwa Majlis Kebangsaan Bagi Hal Ehwal Ugama Islam Malaysia sejak dari tahun 1988 lagi telah mengeluarkan beberapa pandangan hukum yang berkaitan langsung dengan imunisasi yang seharusnya menjadi panduan seluruh umat Islam, antaranya Imunisasi Hepatitis B Menurut Islam, Pandangan Islam Terhadap Imunisasi Campak, Tibi, Batuk Kokol, Difteria, Tetanus Dan Polio, Ubat Pelalian Rubela (Imunisasi Rubela), Hukum Suntikan Pelalian Vaksin Meningococcal Meningitis Oleh Orang Islam, Hukum Penggunaan Vaksin Biothrax Dan Vaksin Rotateq Yang Menggunakan Unsur Babi Dalam Proses Penghasilannya, Hukum Pengambilan Vaksin Human Papilloma Virus (HPV) dan Hukum Penggunaan Vaksin Meningitis Menveo.

Maklumat-maklumat mengenai keputusan tersebut boleh diperolehi melalui Portal e-fatwa (www.e-fatwa.gov.my).

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