

Pediatric research ethics: Islamic perspectives

Key words:

Islam, Medical research, Children

Abstract

Background: Children's participation is crucial in research on childhood diseases and cases associated with childhood health. Despite the existence of many publications that address ethical issues related to the participation of children in clinical research around the world, very little has been written about these ethical issues from an Islamic perspective.

Methods: In this study, we analyzed medical research on children from three Islamic resources: institutional fatawa by juristic institutions, the opinions of Islamic medical organizations and individual writings.

Results: Seven institutional fatawa from three juristic councils could be found. Only four of them raise ethical concerns about research on children. Two documents from medical organizations were identified.

Conclusion: Three different positions could be concluded from these fatawa: an absolute prohibition, restricted permission and permission. Prevention of any harm is a major concern in all fatawa. Guardian's consent is necessary, but more details are needed. The guidelines of Islamic Organization of Medical Sciences IOMS reflect the best available Islamic perspective about research on children.

Introduction

Scientific progress in the fields of biology, medicine, and health relies on research in these areas. Clinical research and medical experiments are important for obtaining better treatments for diseases with the least harmful effects.¹

Many researchers and pharmaceutical companies in the West opt to conduct research in third world countries for economic reasons or because most of these countries do not have strict ethical laws like those in the West.² Moreover, many researchers from developing countries conduct research activities in their own countries, including Muslim countries.³ At the same time, Western scholars have very little knowledge regarding Islamic ethical views on medical issues, including regulations related to medical research, especially on children. Many hear about the Islamic Law, the Sharía, but very few know whether Islamic law on medical issues is compatible with or contradictory to international perspectives on medical research.

Children's participation is crucial in research on childhood diseases and cases associated with childhood health, such as vaccine-related issues, or cases related to drugs designed for children.⁴ In the past, many new

medications were tested only on adults despite the fact that these medications were applicable to diseases that occur in childhood. This is also true for research on stored tissue material from children, which raises distinct ethical challenges with regard to the involvement of adults.⁵ However, children are not simply small adults, and we cannot always apply the results of research conducted on adults to children and young people. This is especially true for the safety of tested medications. Therefore, many research institutions and researchers feel that it is important to conduct research on children.⁶

Medical research in Arab countries is increasing rapidly. The high percentage of children in Arab and Islamic societies (compared to Western societies), as statistics show, makes conducting research on children a crucial issue. For example, according to statistics from 2007, 32.5% of the people in Saudi Arabia are 15 years old or younger.⁷ Medical research on children has made room for ethical debates that reflect the publication of numerous recommendations, ethical laws and guidelines to achieve a balance between the need for children's participation in medical research and the duty to offer them protection and to avoid doing them harm, as expressed in the Declaration of Helsinki (adopted 1964; latest amendment, 2008)⁸ and the International Ethical Guidelines

for Biomedical Research Involving Human Subjects (1982; revised, 2002) by Council for International Organizations of Medical Sciences.⁹

Key ethical issues addressed by bioethicists regarding clinical research on children include the following: first, researchers can conduct clinical research on children only when it aims to address a pediatric problem or to obtain knowledge related to the health needs of children and cannot be feasibly conducted to the same degree with adults; second, researchers should seek the consent of the parents or legal guardians of children participating in the research; third, researchers should obtain the child's assent according to his ability; and fourth, the researchers should respect the child's desire to withdraw from participation in the research.¹⁰

Religious principles (including Islamic rules) form a basis for many practical applications of medical regulations and ethical rules.¹¹ The relationship between Islam and medical research on children has not yet been explored in depth. Despite the remarkable increase in the number of researchers, conducting medical research on children and the existence of many publications that address ethical issues related to the participation of children in clinical research around the world, very little has been written about these ethical issues from an Islamic perspective.

This paper will provide a first step in filling this gap. The objective of this essay is to present Islamic opinions regarding medical research on children through an analysis of key Islamic resources on the Islamic attitude toward research on children.

Methods

In this study, we analyze medical research on children from three Islamic resources: institutional *fatawa* (*Fatawa* is a plural of *fatwa*) by juristic institutions, the opinions of Islamic medical organizations and individual writings. A *fatwa* is a religious opinion concerning Islamic law. It is called a institutional *fatwa* if it is issued by a group in a juristic council and an individual *fatwa* if it is issued by a single scholar.¹² Members of institutional councils are not only religious scholars, but some of them are medical doctors, economists and researchers in different fields. Institutional *fatawa* play an increasingly important role in representing Islamic views of some issues, especially new matters.¹³ We included in our study all Arabic or English, Sunni, institutional *fatawa* that could be accessed online.¹⁴ Our study focused on the Sunni school (87-90% of Muslims are Sunni Muslims and 10-13% are Shia) (Pew Research Center 2009)¹⁵ We excluded individual *fatawa* from our resources

because there is a problem of selection of scholars. Moreover, after a random pilot survey of approximately 20 websites of scholars from various countries, we could not find any individual *fatawa* about research on children. Even more survey of medical *fatawa* mentioned in certain Islamic web used in previous research of *fatawa* about organ donationno *fatwa* related to medical research of children could be found: www.islamonline.net, www.islamweb.net, www.islamicity.com, www.islam.tc, www.islamtoday.com, and www.understanding-islam.com.¹⁶

In a recent review we showed that 13 juristic councils offer online access to their *fatawa*: two international councils, the International Islamic Fiqh Academy (IIFA) and the Islamic Fiqh Council in the Muslim World League (IFC); four regional councils covering Europe, America, the Gulf and Al-Sham (Syria, Jordan, Lebanon and Palestine); and eight national councils in Saudi, Egypt, India, Malaysia, Singapore, Palestine, Turkey, and Jordan.¹⁴ We surveyed all institutional juristic *fatawa* released by these institutions.

For the opinions of Islamic medical organizations, we concentrated on the two leading organizations that could be accessed online in either English or Arabic as found in a previous study: the Islamic Organization

for Medical Sciences (IOMS)

(<http://www.islamset.com/ioms/code2004/index.html>) and the Islamic

Medical Association of North America (IMANA)

(www.imana.org/).¹⁴ Although these are not juristic councils, they are

medical organizations that adhere to Islamic law.

We excluded *fatawa* and opinions about embryonic stem cell research as well as anonymous *fatawa* and opinions on websites that do not represent official parties.

We continued by exploring related articles on the Islamic perspective on medical research on children. These articles were retrieved using search engines in both Arabic and English and by employing the search terms *research+Islam+children*. PubMed was used for English articles, and *The Comprehensive Encyclopedia* (الموسوعة الشاملة) www.islamport.com/ and

The Comprehensive Library (المكتبة الشاملة) <http://shamela.ws/> were used to access Arabic resources. We also accessed the King Abdulaziz Public Library in Riyadh-Saudi and the Jarir and Obeikan bookshops.

We attempt to establish a generalized standpoint on research on children from an Islamic perspective. We analyzed the compatibility of

this research with international views as stated in official documents, such as the Declaration of Helsinki, Good Clinical Practice GCP¹⁷, and the CIOMS guidelines.

Results

Data collection

We retrieved nine different documents covering Islamic perspectives on one or more issues about clinical research (table 1).

We found seven different *fatawa* from three juristic councils between 1992 and 2008. Six of them have an international scope, and the seventh, by *Dar-Aliffta Al-Misrriyah* (Egypt's *Fatwa* House), has a national scope. Only four of them raise ethical concerns about research on children and three address the subject generally.

Two documents from medical organizations were identified. One of them, by IOMS, has an international scope and includes a separate chapter for research on children. The second, by IMANA, has a North American scope and is not specific to children.

The *Dar-Aliffta Al-Misrriyah*' *fatwa* and the IMANA' document addressed stem cells in general. They were included because they were not limited to embryos; they also contained a section on research on adults or children.

We found few individual writings, and none of them could be included in our results because they either presented a Shia point of view,¹⁸ merely repeated *fatawa* and IOMS opinions;¹⁹Fadel,²⁰Abu Matar,²¹ or only contained short comments.

Research on children

We identified two major themes: the position toward conducting research on children and the requirements of research on children: ethics committee approval, best interest of child, no harm, informed consent of guardians and the assent of the child.

There are three different positions expressed by the studied documents.

1) Research on children is not allowed, as clearly stated by *fatwa* IIFA 67: "It is not allowed to conduct medical research on people who lack capacity or incompetents, even after guardian approval".²²2) Research on children is not allowed except there are certain situations, as mentioned by IOM: first situation, there is an exclusive or preponderant interest or an urgent need of the child in the research, even if the child refuses; second situation, it is absolutely necessary to conduct research on childhood diseases and vaccines and drugs related to children.²³*Fatwa* (IIFA 161) accepts IOMS perspectives with regard to

children in research.²⁴ 3) Research on children is allowed; this position is taken by *fatwa* by Islamic Fiqh Council²⁵ regarding stem cells and by *Dar-Alifta Al-Misriyah*.²⁶(Table 2).

Five elements for conducting research on children can be identified in the documents that allow research on children: 1) ethics committee approval was not mentioned in any of the studied *fatawa*, but it is mentioned in IOM guidelines.²³ 2) the best interest of the child himself or the group of children (Council for International Organizations of Medical Sciences. & World Health Organization; International Islamic Fiqh Academy);^{8,9,24} 3) "no harm" is a prerequisite in all documents, even if the harm is only potential harm, as stated in *fatwa*161by International Islamic Fiqh Academy;²⁴ 4) guardian consent is necessary, but none of the documents provide details on who can be a guardian; 5) child assent is not clearly mentioned in any of the documents; however, IOMS states that the assent of the child cannot replace guardian consent.²³

Discussion

Research on children

Only few documents about research on children could be found in Islamic literature. This is compatible with our results of a previous **studyabout** medical research in general in 13 Muslim countries in the Middle East, that showed that only three countries mentioned research on children in their guidelines.²⁷ (see table 3).

In the **fatawa**, we notice three different positions regarding clinical research on children: it is not allowed, it is not allowed except in special situations and it is allowed. At the international levels, the Declaration of Helsinki and the CIOMS guidelines permit research on children under certain conditions.^{8,9}

The oldest **fatwa** (IIFA 67, 1992) issued more than 20 years ago, disallows research on children.²² This prohibition can be explained by a limited awareness about the importance of research on children among the jurists of IIFA, and the lack of a complete and clear understanding of research on children. Moreover, jurists tend to take the safe side that offers better protection of children. This **fatwa** also reflects the poor participation of medical doctors and specialists in the formulation process of this **fatwa**, since medical doctors are not full members in juristic council but they are just consultants.

Since that **fatwa** IIFA 67, many **fatawa** have been issued (IFC 3/17, 2002; IIFA 161, 2006; *Dar-Aliffta Al-Misrriyah* 598, 2008) that allow research on children under certain conditions. That will be discussed below.²⁴⁻²⁶

Islamic Organization Medical Sciences faced a challenge in dealing **fatwa** (IIFA 67), which disallowed research on children. IOMS agrees to this prohibition, but then it provides two exceptions to allow research on children. These exceptions are: first, the research must be beneficial or address an urgent need for the child; second, there must be a general need for research on childhood diseases, provided that the potential risks are minimal.

The different positions between the IOMS opinion and IIFA's **fatwa** 67 can be attributed to the difference in the composition of the teams that formulated the documents. In contrast with the IIFA, the IOMS, which was originally an Islamic-oriented medical institution, has a drafting committee composed of scholars in law and medical doctors and experts in medical research, and one of them is not even a Muslim.²³

Conditions for research on children

Looking at the conditions in which the research on children is possible, the following five conditions are mentioned: 1) Ethics committee

approval of any research on children must be collected, 2) any research must be in the best interest of child, 3) risk of any research must not be more than minimum risk (do no harm), 4) consent must be collected from the child guardian, and 5) if possible the assent of the child should be sought for. In the following, we discuss these five conditions in an Islamic perspective compared them with international guidelines.

Ethics committee:

None of the *fatawa* refers to ethics committees. Only IOMS talks about the obligation of approval by research ethics committees prior to research on children. The obligation of an ethics committee approval has been mentioned in many international guidelines, such as the Declaration of Helsinki, the CIOMS, and now is considered one of the most important mechanisms to offer protection to research participants especially when children are involved.

Best interest of child:

Fatwa IIFA 161 and IOMS mention the best interest as one of the conditions for allowing research on children. For IOMS the best interest of child is either the beneficence of the individual child, or the beneficence of childhood community. This implies that therapeutic

research, in contrast with IIFA 67 can be interpreted in a broader way: not primary beneficial of individual child but beneficial to children in the same age.

In Islam, even if guardians can decide for the children's affairs, their decisions must always be in the best interest of the child. It is the parents' responsibility to provide care and protection for their children. Similarly, many Muslim²⁸ and Western²⁹ scholars agree that any decision of the parents must be considered within this framework. Taking into account the best interest of the child is the most obvious of respecting the child as a human being.^{28,30} The best interest of child is a major concern in research on children and is mentioned in the Declaration of Helsinki and the IOMS opinion.^{8,23}

Do no harm:

The principle "do no harm" is stated by all documents including IOMS guidelines.

Both in Islam and internationally it is accepted that children are a vulnerable group;^{31,5} their protection is the responsibility of their guardians and the community at large. The government has the responsibility of controlling this protection through its regulations. This

is clearly mentioned in *fatwa* (IIFA 161), which withdraws parental approval if the research causes harm to the child. This *fatwa* is consistent with the statements of Muslim scholars' statements that the relationship between parents and children is not just a relationship of mercy and compassion but is also a relationship based on responsibility of parents toward their children, in raising them and offering them better care.³²

Although the documents in this study agree that any medical research to be performed on a child should not cause harm to that child, they do not define or specifically note the harm or its degree or state before it is possible to conduct research with minor risks. Only IOMS specifies that the potential risk should be minimal when conducting research on children. "Minimal risk," as stated by many authors in the west, is one of the criteria for allowing research on children.³³

Guardian consent:

Medical research can be conducted only after obtaining informed consent from the *participant*, if he is an adult, or from the guardian, if the *participant* is a child or is unable to give consent. Three *fatawa* IFC 3/17, IIFA 161 and *Dar-Alifta Al-Misriyah* (598) and IOMS require

getting guardian informed consent prior any research conducted on children. This prerequisite is also required in the international research ethics guidelines, such as the Declaration of Helsinki and CIOMS guidelines. It is also explicitly mentioned in the writing about ethics of research on **children** in both documents and individual writings.^{8,9,34}

Fatawa use word the "guardian", but they do not provide details about who is considered a guardian. The Helsinki Declaration in the context of incompetent **participant** uses "authorized representative" while the CIOMS speaks about "guardian or parents". The Islamic position regarding who is a guardian, can be deduced from other **fatawa** or juridical sources such as Al-Mausoha Al-Feqhia (Juridical Encyclopedia) by the Ministry of Awqāf and Islamic Affairs.³⁵ For Islamic resources generally define the guardian in issues like the child's inheritance, but not for medical research or medical issues. Some authors, such as Shankeeti,³⁶ favor applying the general definition of guardians for medical issues. Consequently, the priority of the guardians of a child can be classified as follows: parents, then grandfathers, and then adult brothers, respectively.

Child assent:

Except for the IOMS opinion, child assent in research ethics is not mentioned in any of the documents. None of documents describes from which age on a child can give assent or when it becomes an adult and gives consent. Although not explicitly given a certain age for medical maturity, the CIOMS and the Helsinki Declaration mention to the importance of considering child opinion.^{8,9} CIOMS stated that from 12-13 the child opinion should be taken into account.⁹

An overview of regulations about the position of children in health care has shown that the age under which children can take decisions related to their health varies from country to country.⁵ The ability to take decisions depends on the degree of capacity, which differs from one child to another and is affected by many factors, such as personal abilities and social context.^{33,34} A study by Stultiens et al. shows three different types of the relation between medical maturity and legal maturity: 1) they are the same, 2) they are different and 3) medical maturity must be studied case by case depending on age and maturity.³⁷ For Islam we can return to the Al-Mausoha Al-Feqhia (Juridical Encyclopedia),³⁵ which identifies the age of majority in financial and criminal issues, but not in medical issues. It divides ages to three levels. At the first level, a child's decisions cannot be accepted when he/she is

under the age of seven because he/she cannot understand the nature of the issue. At the second level, from seven years old to majority, we can only accept those decisions that are both correct and do not cause harm to the child. Decisions by children that are not to be considered correct, and/or cause harm to the child can be rejected by the guardian. The third level is majority. (Table 4t) Al-Mausoha Al-Feqhia did not define a specific age for a child to be considered an adult; it referred to the laws of each country. For example, the official documents of some Muslim countries stipulate different ages of majority: 18 years for Jordan,³⁸ 19 for Algeria,³⁹ 20 for Tunisia⁴⁰ and 21 for Egypt (1948).⁴¹

Conclusion

Despite the importance of the ethics of medical research on children, there are few Islamic documents on the subject, and they do not reflect the importance of this subject. The **fatawa** are brief and do not cover all aspects of the ethics of research on children. In ideas like assent and consent, **fatawa** do not develop a specific theory, but refer to other resources. Three different positions could be distinguished from these **fatawa**: absolute prohibition by the oldest **fatwa** (IIFA 67), restricted or conditioned prohibition and permission by the **fatawa** later. Most of the

conditions of research on children presented in the international guidelines like the Declaration of Helsinki and the CIOMS can be found in the **fatawa**, although a single **fatwa** does not mention all international conditions. However, the international requirement of approval by ethics committee cannot be found in the **fatawa**.

The detailed IOMS document is important and represents the most balanced available document that provides an Islamic perspective on clinical research ethics in general, including research on children. The view provided by IOMS is mostly compatible with international guidelines and the best practice.

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Table 1: Institutional fatwas about research on children

Year	Type of resource	Title	Subject	Author	Background of author	Scope	Size of document	
							Total document	The part about children
1992	Institutional fatwa	Decision 67 about medical treatment	Informed consent No harm Lacking capacity or incompetent	International Islamic Fiqh Academy IIFA	Juristic Council	International	73 lines	1 line
1997	Institutional fatwa	Decision 94 about cloning	Encourage research Cloning Genetic engineering	International Islamic Fiqh Academy IIFA	Juristic Council	International	105 lines	-
1998	Institutional fatwa	Decision 1/15 about genetic engineering	Genetic research Informed consent	Islamic Fiqh Council IFC	Juristic Council	International	48 lines	-
2002	Institutional fatwa	Decision 3/17 about stem cells	Stem cells research Informed consent Research on children	Islamic Fiqh Council IFC	Juristic Council	International	24 lines	1 line

2004	Institutional fatwa	Decision 142 about doctor responsibility	Encourage research	IIFA	Juristic Council	International		
2005	Opinion	International Ethical Guidelines for Biomedical Research Involving Human Subjects - An Islamic Perspective	All research ethics issues presented in CIOMS, including research on children	Islamic Organization for Medical Sciences IOMS	Medical Organization	International	190 pages	2 pages
2006	Institutional fatwa	Decision 161 Islamic controls of biomedical research on humans	Research integrity Approving of Islamic perspectives of CIOMS by IOM Informed consent Protection (even from guardian) of those lacking capacity or incompetent	International Islamic Fiqh Academy IIFA	Juristic Council	International	60 lines	4 lines
2008	Institutional fatwa	Using of stem cells in research (598)	Stem cells research Informed consent Research on children	Dar-Alifta Al-Misrriyah	Juristic Council	National (Egypt)	25 lines	1 line

No date	Opinion	Stem Cell Research: the IMANA perspectives	Genetic research & engineering Stem cells research Conceive to abort the fetus to obtain stem cells	Islamic Medical Association of North America IMANA	Medical Organization	Regional (North American)	16 pages	2 lines
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Table 2: Ethical concerns in research on children in Islamic resources

Document	IIFA 67	IFC 3/17	IOMS	IIFA 161	Dar-Alifta Al-Misrriyah (598)
Date	1992	2002	2005	2006	2008
Permission for research on children	No	Yes	No unless	No unless	Yes
Best interest of child	Not applicable	Not available	Yes	Yes	Not available
Obligation of guardian consent	No	Yes	Yes	Yes	Yes
No harm	Yes	Yes	Yes	Yes	Yes
Child assent	Not applicable	Not available	Yes	Not available	Not available
Ethics committee	Not available	Not available	Yes	Not available	Not available

Table 3: Children's research ethics in the guidelines of some Arab Middle Eastern countries

	Egypt	Saudi	Qatar
Guardian consent	Yes	Yes	Yes
Child assent	-	Yes	Yes
Best interest of child	Yes	Yes	Yes
No more than minimal risks	-	Yes	Yes
Ethics committee	-	Yes	Yes

Table 4: Levels of ages according to Al-Mausoha Al-Feqhia.

Stage	Technique	Child's Actions		
Before the age of distinction	<7 years	Invalid		
Age of distinction (financial issues)	>7 years	Beneficial	Neutral	Harmful
		Valid	Related to other party	Invalid
Adult age (financial or criminal issues)	Majority age (defined by government)	Valid		