

# Egyptian Patients'/guardians' experiences and perception about clinical informed consent and its purpose: Cross Sectional Study

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## Research article

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## Egyptian Patients'/guardians' experiences and perception about clinical informed consent and its purpose: Cross Sectional Study

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### *Abstract*

**Background:** Informed consent (IC) is a healthcare standard emphasizing the meaning of human dignity as clarified in The Universal Declaration of Human Rights. Data about IC practices in Egypt is insufficient. This study aimed to describe the Egyptian patients 'or guardians 'experience about IC and their expectations about its meaning in general and according to type of healthcare facility.

**Methods:** Self-administered questionnaire to 1092 participants who had undergone or were scheduled to a procedure requiring an IC at three types of Egyptian health care facilities. Ten statements were ranked twice by the participants to reflect their perception of IC purpose as per what is currently practiced then as per what they believe should be practiced.

**Results:** Informed consent implementation varies across the different levels of health care facilities in Egypt; being implemented the most at the non-governmental health facilities (in 85.9 % of procedures) followed by the governmental health care facilities (77.8 %) and the least at the university hospitals (63.8 %). Current practice was perceived to: "Help patient/guardian decide", "Document patient's/guardian's decision", and "Have shared decision" (ranked 1–5 by 64.9%, 59.3 %, and 57.3% of respondents, respectively). The perceived purpose of IC was to: "Inform the patient/guardian", "Make sure patient/guardian understand" and "Document patient's/guardian's decision" (ranked 1–5 by 68.4%, 65.3 %, and 65.1% of respondents, respectively).

**Conclusion:** The use of IC is common in Egyptian medical practice but varies across healthcare facilities. Participants believe that the current purpose of IC is to help in decision making, and its main purpose should be information disclosure. There is consensus agreement that both documenting the patient's/guardian's decision and informing the patient /guardian is considered as important current as well as preferred practices. IC should be an integral part of any procedure with more emphasis on seeking assent children whenever appropriate.

**Keywords:** Informed consent, Arab Culture, Norm perception, Current practice.

### **Background:**

Informed consent is a fundamental principle of health care. It is the process whereby the patient or guardian and the health care practitioner engage in a dialogue about a proposed medical treatment nature, consequences, harms, benefits, risks, and alternatives [1]. Through this process, the health care provider discloses appropriate information to a competent patient or guardian so that the patient or guardian may make a voluntary choice to accept or refuse treatment [2]. Informed consent process is linked to sustainable development goal no 3 (good health and wellbeing) and goal 10 (reduce inequalities). [3]

The purpose of the informed consent process ranges from being a routine paper work, to ideally enabling patients' self-decision-making. It has been perceived by some patients and clinician as a mean to fulfill the social requirement of giving more authority to the customers in health care. Philosophically, the informed consent is founded on the principle of Respect for Persons, which includes not only respect to autonomy but also to liberty and wellbeing [4, 5].

Opinions vary regarding the amount of information that needs to be given to patients prior to any procedure. A debate about the role of consent exists with some arguing that there is 'no need to warn about the risks inherent in all surgery under general anesthesia', and others arguing that patients should be should be warned about 'all-risks' [6].

The quality of informed consent in clinical practice is influenced by many factors [7]. These factors could be patient related such as the educational level. Also, patient age seems to be associated with the outcome of informed consent e.g. aging physical impairment may affect the process and result of informed consent [8]. Hence, parents or caregivers should generally be recognized as the appropriate ethical and legal surrogate medical decision-makers for their children and adolescents and in cases of emergency. This recognition affirms parents' familiar understanding of their children's affairs and respects family autonomy [9]. Being identified as a vulnerable group is another sociodemographic factor that most probably leads to incomplete, ineffective, decision-making process [10].

The concept of informed consent has a long history. Its origins date back to the ancient Egyptians times, when doctors believed that their medicines had to benefit their patients while not being detrimental [11]. In the 1970s, the informed consent was embraced as a correction to paternalism, however, in the 1980s and 1990s, shared decision-making was viewed as a necessary correction of "exaggerated individualism" [12]. The current concept of informed consent developed on a principle which states that the fundamental element of doctor-patient relationship is based on the patient's free choice to undergo the proposed medical procedure [11].

As historical background about the use of formal informed consent for surgery in the Islamic/Arabic culture, it dates back at least to the 17th century [13]. It originates from the legal and ethical right the patient has to decide what happens to his/ her body and from the ethical duty of the physician to involve the patient in his/her health care [14].

In Egypt, informed consent and sharing information are among the mandated Egyptian patient's rights since 2005 [15] along with other rights such as access to health care, choice of care, health education, participation in treatment plan, confidentiality and privacy [16-19].

There is however a lack of information about the practice of informed consent provision in Egyptian society and the individuals' expectations about its role. This study aims to describe the current practice of informed consent provision and to explore whether it is implemented equally at different types of health care facilities in Egypt or not. It aims to assess also the opinions of the patients and parents of ill children and adolescents about its purpose. The outcome of this research is expected to enlighten the health care policy makers about any required modification of the current informed consent process.

### **Methods:**

Multi-centre cross sectional exploratory research was conducted. The study participants were randomly selected to represent users of three different health care settings in Egypt, including; governmental (Ministry of Health) organization, non-governmental (private) organization and the university (public teaching) hospital which are named respectively; Governorate and primary health care centres at El Mansoura Governorate, Liver Hospital in Dakahlia, El Mansoura university hospital, the Egyptian. The facilities were selected based on accessibility, geographical coverage, and diversity of attending patients. Data was collected over a six month period (June- December 2017).

Participants were randomly selected from adult patients and parents of ill children and adolescents who had undergone medical or surgical procedures requiring a specific written informed consent over the previous three months or were scheduled to undergo one within the following three months.

Sample size calculation was based on the following assumption per setting: a two-sided 95% confidence interval with a width equal to 0.100, sample proportion of 0.5 assuming that 50% are informed to provide the maximum width for a confidence interval with the calculated sample size. Accordingly, the calculated sample size was equal to 402 per setting. On adding 10 % expected losses, a sample size of 440 participants per setting was required to ensure accuracy of the data [20].

The self-administrated anonymous questionnaire used was a reviewed version adapted from Hammami [21] with author's permission. Participants received explanation and gave their verbal consent to participate. Data was collected about participants' demographics, procedure type and informed consent process. The questionnaire consisted of two parts each of ten statements about potential purpose of informed consent process which were presented to participants in a random order. One part was considering participants' perception of current purpose at the study institutions and the other part about their perception of the preferred purpose. Participants were then instructed to rank the ten statements in each part on a ten-point scale in which 1 was "most reflective" and 10 was "least reflective". The ten statements abbreviations are listed in Table 3.

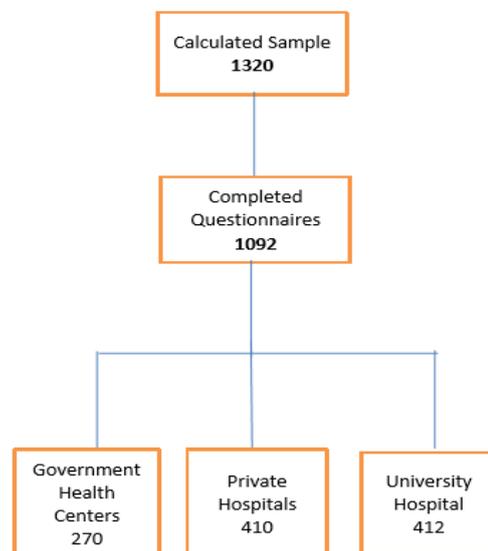
The study was approved by the Research and Ethical Committee of the National Research Centre, Medical Research Ethics Committee of the National Research Centre Egypt with ethical registration no 16051. The conduct of the study complied with the International Ethical Guidelines for Biomedical Research Involving Human Subjects [22].

Data was analysed using SPSS version 20. The grouping by the three health care facilities applied to tackle confounding problem. \*Kruskal-Wallis and Wilcoxon Signed ranks tests were used to compare statement ranking. The level of significance used was 95% with alpha=5%.

## **Results:**

**Figure 1: The response rate among the study facilities**

The overall response rate is 83 %. The refusal rate was highest among the governmental health facility (270 out of 420 with 64 % response rate) claiming that they are busy and are not able to fill in the questionnaire.



**Table (1)** Sociodemographic characteristics of the study participants according to the type of the healthcare facility

	<b>Governmental Primary Healthcare centers</b>	<b>Non- governmental hospital</b>	<b>University hospital</b>
<b>No. of study participants</b>	270	410	412
<b>Age in years [mean ± SD]</b>	44.4±13.33	51.46±12.16	50.89±11.73
<b>Gender [no. (%)]</b>			
Male	136(50.4)	236(57.6)	155 (37.6)
Female	134(49.6)	174(42.4)	257 (62.4)
<b>Marital status [no. (%)]</b>			
Single	12(4.4)	15(3.7)	11(2.7)
Married	240(88.9)	365(89.0)	369(89.6)
Divorced	1(0.7)	7(1.7)	23(5.6)
Widow	17(5.9)	23(5.6)	9(2.2)
<b>Type of medical procedure [no. (%)]</b>			
Elective	174(64.4)	336(82.0)	257(62.4)
Emergency	96(35.6)	74(18.0)	155(37.8)
<b>Information provided [no. (%)]</b>			
Enough info	210(77.8)	352(85.9)	263(63.8)
Not enough info	60(22.2)	52(12.7)	84(20.4)
No info applied	0 (0.0)	6(1.5)	65(15.8)
<b>Type of consent [no. (%)]</b>			
Written consent	248 (91.9)	394(85.1)	250 (60.7)
Oral consent	14 (5.2)	54(13.2)	115(27.9)
No consent	8 (3)	7(1.7)	47(11.4)

- no.: count.

Out of the 1092 participants who filled in the questionnaire, 48.3 % of them were males with the highest males' participation occurring at the non-government hospital (57.6%). Considering the type of procedure undergone, elective procedures were higher than emergency procedures, especially in the non-governmental hospital (82%). with the highest males' participation occurring at the university hospital (62.4%)"

Considering the type of informed consents provided to the patients, parents or other caregivers, written consent was the most common, written consent was most common in the primary healthcare center followed by the non-governmental hospital then by the university hospital (91.9%, 85.1% and 60.7% respectively). The percentage of participants who reported that "enough information" was provided to them during the informed consent process was high in the three groups especially among the non-governmental hospital group. "No information provided" was higher among the university hospital group (15.8%) compared to the other two settings. It was also observed that for any procedures concerning children and/or adolescents, their guardians always talk on their behalf without considering any

consultation with them. Guardians represented 45.79% of the participants (500 out of 1092) , 204 (40.8%) from Governmental Iry Healthcare centers, 140 (28%) from university hospital, 156 (31.2%) from Non-Government Hospital.

**Table (2):** Factors influencing participants’ perception of amount of information received during the informed consent process.

	<b>Enough information received [n: 825 (75.6%)] Count (%)</b>	<b>Little or no information received [n:267( 24.4%)] Count (%)</b>	<b>p-value</b>
<b>Gender</b>			
Male	590(71.5)	39(14.6)	0.001*
Female	235(28.5)	228(85.4)	
<b>Place of the study</b>			
Governmental Iry Health Care Centers	210 (25.5)	60 (22.5)	<0.001*
Non-Government Hospital	352 (42.7)	58 (21.7)	
University Hospital	263 (31.8)	149 (55.8)	
<b>Medical Procedure:</b>			
Elective	584 (70.8)	183(68.5)	0.77
Emergency	241 (29.2)	84 (31.5)	

n.: number of participant. \* Significant P-value

Receiving enough information during the informed consent process reported by almost three quarters (75.6 %) of the interviewed participants. Those who reported receiving little or no information during the IC process were significantly likely to be female (85.4 %). When comparing the information received by place of the study, the least received information was significantly reported among those who were interviewed at the university hospital (55.8 %) irrespective of the types of the medical procedures they are exposed to ( $p>0.05$ ). Participants who reported receiving enough information were significantly found among those who interviewed in the non-government hospital (42.7%).

**Table (3): Comparison between patients' perceptions of current and preferred practices of informed consent among the study facilities:**

Statement	Current Practice Mean± SD Median (25%-75%)				Preferred Practice Mean± SD Median (25%-75%)			
	Governmental Primary Healthcare center(n=270)	Non- government al hospital (n= 410 )	Universit y hospital (n= 412 )	p-value	Governmental Primary Healthcare center(n=270)	Non- governmenta l hospital (n= 410 )	University hospital (n= 412	p-value
“Help patient/guardian decide”	5.7 ± 2.8	5.7 ± 2.7	4.4 ± 3.2	0.027	5.2 ± 2.9	6.7 ± 2.7	5.4 ± 3.3	<0.001
	5(3-8)	4(2-7)	4(2-7)		4(2-7)	6(3-8)	4(2-7)	
“Make sure patient/guardian understand	6.3 ± 2.7	6.0 ± 2.9	6.1 ± 2.9	0.006	5.7 ± 2.9	5.4 ± 2.8	4.4 ± 2.9	0.006
	6(3-8)	6(4-9)	6(5-8)		6(3-8)	4(2-7)	5(3-6)	
“Inform patient/guardian”	5.0 ± 2.8	4.5 ± 2.7	4.4 ± 2.7	0.616	6.1 ± 2.4	6.7 ± 2.9	6.8 ± 2.9	<0.001
	5(2-7)	5(3-7)	5(3-7)		6(3-8)	4(2-6)	3(2-6)	
“Have shared decision”	5.5 ± 2.9	4.8 ± 2.8	4.7 ± 2.7	0.058	6.4 ± 3.0	6.3 ± 3.2	7.1 ± 3.0	0.006
	5(2-7)	5(2-7)	5(3-7)		5(3-9)	6(4-9)	7(5-8)	
“Discover patient’s preferences”	6.5 ± 2.8	6.2 ± 3.1	6.7 ± 3.4	<0.001	5.5 ± 2.7	4.7 ± 2.7	4.2 ± 2.6	<0.001
	4(2-6)	5(3-7)	6(4-8)		5(3-7)	5(4-7)	6(5-7)	
“Document patient’s/guardian decision”	4.8 ± 3.0	4.7 ± 2.7	5.0 ± 2.4	0.014	5.5 ± 3.1	4.1 ± 2.4	4.1 ± 2.6	<0.001
	6(3-8)	4(3-7)	4(2-7)		5(3-8)	5(2-6)	3(2-6)	
“Litigation protection”	4.7 ± 2.7	4.9 ± 2.6	5.0 ± 2.5	<0.001	4.7 ± 2.9	4.4 ± 2.6	5.0 ± 2.4	0.305
	6(4-8)	6(4-8)	4(1-8)		5(3-8)	6(3-7)	5(4-7)	
“Courtesy gesture”	4.5 ± 2.8	5.2 ± 2.6	5.7 ± 2.5	0.000	5.1 ± 2.8	5.2 ± 2.5	5.5 ± 2.4	<0.001
	5(3-9)	8(5-10)	7(5-8)		5(3-8)	7(4-9)	6(1-8)	
“Take away compensation rights”	5.7 ± 2.6	5.9 ± 2.8	6.4 ± 2.4	0.457	5.1 ± 2.6	5.5 ± 2.6	5.9 ± 2.3	0.002
	7(4-9)	6(4-9)	6(3-9)		6(4-8)	8(4-9)	8(4-9)	
“Meaningless routine”	5.7 ± 3.0	7.0 ± 2.8	6.5 ± 2.6	0.012	7.0 ± 2.8	6.0 ± 2.8	6.5 ± 2.4	<0.001
	7(5-9)	6(4-9)	8(3-10)		6(4-9)	7(3-10)	8(4-10)	

SD: standard deviation. IQR: (25%-75%):.\* P-value is for Kruskal-Wallis test

Table (4) Differences between patients' perception of current and preferred practices of informed consent in each of the study facilities:

Statement	Governmental 1ry Healthcare center(n=270)			Non-governmental hospital (n= 410 )			University hospital (n= 412 )		
	Current	Preferred	P-value	Current	Preferred	P-value	Current	Preferred	P-value
"Help patient/guardian decide"	5(3-8)	4(2-7)	.044	4(2-7)	6(3-8)	<.001	4(2-7)	4(2-7)	.793
"Make sure patient understand"	6(3-8)	6(3-8)	<.001	6(4-9)	4(2-7)	<.001	6(5-8)	5(3-6)	<.001
"Make sure patient/guardian understand"	5(2-7)	6(3-8)	.053	5(3-7)	4(2-6)	<.001	5(3-7)	3(2-6)	<.001
"Have shared decision"	5(2-7)	5(3-9)	.006	5(2-7)	6(4-9)	<.001	5(3-7)	7(5-8)	<.001
"Inform patient/guardian"	4(2-6)	5(3-7)	.073	5(3-7)	5(4-7)	.133	6(4-8)	6(5-7)	.279
"Document patient's decision"	6(3-8)	5(3-8)	.945	4(3-7)	5(2-6)	.416	4(2-7)	3(2-6)	.012
"Have shared decision"	6(4-8)	5(3-8)	.119	6(4-8)	6(3-7)	.015	4(1-8)	5(4-7)	<.001
"Courtesy gesture"	5(3-9)	5(3-8)	.188	8(5-10)	7(4-9)	.052	7(5-8)	6(1-8)	<.001
"Discover patient's preferences"	7(4-9)	6(4-8)	.360	6(4-9)	8(4-9)	<.001	6(3-9)	8(4-9)	<.001
"Meaningless routine"	7(5-9)	7(4-9)	.830	6(4-9)	7(3-10)	.668	8(3-10)	8(4-10)	.025

\*P-value is for Wilcoxon Signed ranks test.

As shown in Tables 3 and 4, two statements were found to be ranked significantly different in the current and preferred practice of informed consent in the three healthcare settings. These were "Make sure patients/guardians understand" (higher median rank in the preferred practice ranking) and "Have shared decision" (higher median rank in the current practice ranking). Three statements were found to be ranked significantly different in the current and preferred practice of informed consent in the university and non-governmental hospitals, namely: "Inform patients/guardians" (higher median rank in the preferred practice ranking) and "Take away compensation rights" and "Litigation protection" (higher median rank in the current practice).

**Table (5):** Comparison of percentage of high ranked statements in current and preferred patients' perception Informed consent practices:

Statement	Current practice	Preferred practice
	Total	Total
Help patient/guardian decide	64.9%	54.5%
Document patient's/guardian's decision	59.3%	65.1
Make Shared decision	57.3%	Not highly ranked
Inform patient /guardian	56.8%	68.4%
Litigation protection	54.6%	51.4%
Make Sure patient/guardian understand	Not highly ranked	65.3%
Discover Patient/guardian preference	53.8%	Not highly ranked

Table 4 depicts in percentages the statements with the highest rank (1-5) in the three sites as perceived by patients in the current practice and preferred practice. The three statements with the best overall ranks considering the current practice are: “Help patients/guardians decide”, “Document patient’s/guardian’s decision”, and “Make shared decision”. These were ranked 1–5 by 64.9%, 59.3 %, and 57.3% of respondents, respectively. The three statements with the best overall ranks considering the preferred practice are: “Inform the patient/guardian”, “Make sure patients understand” and “Document patient’s decision”. These were ranked 1–5 by 68.4%, 65.3 %, and 65.1% of respondents, respectively.

### **Discussion:**

The study target population was matched with the topic as it is more relevant to assess the perception of clinical informed consent among persons who experienced the process in reality which support the validity of the study conclusion. Testing the study hypothesis among high number of participants with wide diversity attending more than one health care setting makes the findings more reliable and generalizable. The current consent practice was perceived to: “Help patient/guardian decide”, “Document patient’s/guardian’s decision”, and “Have shared decision” (ranked 1–5 by 64.9%, 59.3 %, and 57.3% of respondents, respectively). The perceived purpose of informed consent was found to be: “Inform the patient/guardian”, “Make sure patient/guardian understand” and “Document patient’s/guardian’s decision” (ranked 1–5 by 68.4%, 65.3 %, and 65.1% of respondents, respectively).

As found in this study written consent is the predominant tool for informed consent process which is still the preferred method for pre-operative anesthetic counseling. Visual consent had the strongest influence on parents' comprehension [23] and could hence be used to enhance the process of informed consent. Using multimedia tools help in lowering patient anxiety during informed consent process [24] The majority of participants reported that they receive enough information during the consent process. Measuring the adequacy of information provided is a controversial issue. Many literatures recommend the reasonable patient or guardian standard approach; which focuses on considering what the average patient or guardian would need to know in order to be an informed participant in the decision. This was found as the best approach in order to provide the best care to patients and to respect the patients' rights to be involved in their health care decision [12, 19, 25-27].

The statement of "Inform the patients/guardians" was ranked by the majority of participants as the most desired/expected purpose of the informed consent. This finding supports other studies which showed that patients require the doctor to inform them about all possible complications just to have a better idea of what to expect regardless of whether he is going to use this information to decide to undergo the procedure or not [27]. Moreover, in his study, Leino-Kilpi mentioned that it should be presumed that all patients/guardians wish to be well informed about the benefits and risks, and that paternalistic assumptions are not acceptable [28]. However, patients still vary in the degree of details they want to know, so the surgeon should calibrate the information in accordance to the request [29]. Information given to children and adolescents has to be given under medical care and with appropriate manner whenever possible [9]. In most countries, the legal framework for consent requires parental or guardian permission for young people aged below 18 years. Further, maintaining the role of parents as decision-makers for their child's health care was frequently prioritized over enabling young people's autonomy to consent [30].

Patients/guardians do not only care about the amount of information received, but also about its quality and clarity. "Make sure patient/guardian understand" statement was reported with highly significant difference of preferred practice versus current practice. Patients'/guardians' demographic, socio-economical aspects, clinical history and listening attitude are among the factors that affect patients' ability to receive information clearly [15].

The three statements of "Help patient/guardian decide", "Document patients'/guardians' decision", and "Have shared decision" were ranked high by the majority of participants when ranking statements based on the current perceived purpose of informed consent. Also, "Have shared decision" statement was reported with highly significant difference of current practice versus preferred practice. Similar findings were presented in Ferrarese et al., study which reported that making a joint decision between patients

or guardians and their physicians was more frequently reported compared to assigning more responsibility to the physician or giving patients or guardians full autonomy [11]. Physicians should involve pediatric patients in their health care decision-making by providing information on their illness and options for diagnosis and treatment in an appropriate manner with seeking assent to medical care [9].

The majority of participants gave a low rank for the statement of a “meaningless routine” which indicates that they believe in the importance of the process of informed consent. Similar findings were reported by other studies as a minority of respondents perceived the clinical informed consent as a “courtesy gesture” [21, 31].

Our results showed that the non-governmental (private) organization reported the highest percentage of giving enough information, while the university (Public teaching) hospital was reported the highest for not giving enough information with significance difference. A recent study conducted in Kuwait also reported that consent procedures appear inadequate in governmental hospitals and hence consenting in its current form is not informed and should be re-evaluated to achieve patient autonomy [32]. Similar findings were also documented in a recent study conducted in Azribigan to assess informed consent process in private and public health care institution. Azribigan’s study documented that the IC form in private hospitals are more informative for the patient and represent the real personalized content of the individual case of the patient, while the form used in public hospital looks like a document just to prevent the doctor and institution from possible future complaints in case of negative outcomes of the treatment [33]. Another possible justification in this current Egyptian study could be related to the fact that most of the procedures experienced by the participants were elective procedure in which there is enough time to give enough information. However, the evidence from the systematic review done by Flynn et al. did not support the notion of accepting that emergency procedure is an excuse for incomplete or unsuccessful informed consent process [34]. Furthermore, the American Academy of Pediatrics (AAP) recommends that Physicians have both a moral obligation and a legal responsibility to question and to contest both the surrogate’s and the patient’s medical decisions wherever indicated especially if the patient is exposed to significant risk of serious harm [9].

Receiving “little or no information” was reported as the highest among university hospital participants. This could, at least in part, be explained by the fact that most of these participants were females who may be either neglected deliberately or not deliberately to be informed. This is also supported by an Egyptian study that promoted raising women awareness about their rights and considering it to be mandatory especially for rural communities [18]. Also our study showed significance difference

between both genders in the perception of amount of information received in which high percentage of female reported receiving “no enough information”.

Research that aims to study people’s perception is likely influenced by cultural expectations. Patients’ perception about informed consent has been studied on the basis of the resolution rendered by the Committee of Senior Ulama (Arabic for religious scholars). This Islamic reference explained the perception of some common rules based on Quran and Sunna. For example, Al Quran encourages shared-decision making, it says, “And consult them in affairs.” (Chapter 3, verse 159). Quran also prohibits following others blindly without knowing their evidence (Chapter 33, verse 67; Chapter 43, verse 22; and Chapter 2, verse 111) [35]. Moreover, evidences from Quran and Sunna encourage taking good care of one’s body as well as seeking treatment (Chapter 16, verses 68–69 and Chapter 2, verse 195) [35], and Prophet Muhammad said, "There is no disease that Allah has created, except that He also has created its remedy." (Sahih al-Bukhari 5678) [36]. Reaching 16 years old is the age taken by The 1989 Children’s Act to consider children capable of understanding and making decisions. Islam considers age of majority as a physiological one, in males it is marked by first nocturnal emission and in females it is marked by menarche [37]. Yet, diversity in perception in the same community is still expected and can be justified by several thoughts related to same standard which is applied in Islamic society where Muslims come from several schools. There are differences in national legal regulations when a child has the full right to give his or her autonomous consent [38]

It is expected that Christian teachings also played a role in shaping the perception of Christian participants in our study. Christian scripture encourages the practice of counseling in verses like “Seek counsel always of a wise man” (Tobit book, chapter 4, verse 19), and “The way of a fool is right in his own eyes, but he that hearkened unto counsel is wise” (Proverbs book, chapter 12, verse 15). Also informed consent is a practice which reflects honesty which is a value highly encouraged by Christian scripture in verses like “Open the gates that the righteous nation may enter, the nation that keeps faith” (Isiah book, chapter 26, verse 2).

Religious aspects also shaped the Egyptian community opinions which were reflected in our study by the general agreement about importance of informed consent process with diversity in understanding its purpose [34]. Physicians must realize that informed consent, assent or refusal constitutes a process, not a discrete event, and requires the sharing of information in ongoing physician patient or family communication and education [9]. This is also supported by many of the Egyptian studies about the effectiveness of increasing the awareness about their rights in receiving care especially among rural communities who always reported underutilization for the health services [16-19].

Almost half of the participants in our study were guardians of children and adolescents (45.79%) who are legally authorized for decision making on behalf of their kids. As per American Academy of Pediatrics, It is recommended to include children opinion in decision making process [9]. That recommendation is also supported by The National Council for Childhood and Motherhood in Egypt who emphasize to empower all children whether their sex or background to say their opinions and share in decision making in all aspects of life [39]. Moreover, the information given to children should be age appropriate [40]. On the other hand researchers found sometimes a conflict between child best interest and the decision of parents as in some cases where the treatment is painful or has side effects like in the case of cancer therapy, sometimes parents refuse such painful management and seek for alternatives [41].

### **Limitations of the study:**

It may be taken into consideration that not all participants clearly understood the statements during ranking process. However, such possible bias was minimized by providing explanation to the participants by the attended study investigators prior to fill in the questionnaire. Also, the consistency of responses observed among most of the participants may indicate that the final conclusion not affected much by the assumed participant misunderstanding. Another important concern that according to study aim and method, only patients experience and perception were considered for assessment of the informed consent process. However, it may be helpful to consider third party evaluation by observing healthcare providers- patients communication during the informed consent process to detect drawbacks if any and raise practical recommendations to improve the process of informed consent.

In conclusion, patients and parents of ill children and adolescents vary in their perception about the purpose of the informed consent. However, the majority of participants agreed about its importance and reported that they receive enough information during the informed consent process but with varied percentage according to the type of the health care setting. The currently practiced consent process was perceived to be a decision making guiding process, while the participants' preference is more toward the purpose of getting more information disclosure than involvement in decision-making. So additional information is recommended which includes but not limited to surgeon experiences and procedure expected outcomes with much more emphasis on making sure patient/guardian understand, document patient's/guardian's decision and informing patient /guardian rather than sharing decision making. Actions to improve and standardize the content of informed consent are recommended for all categories of healthcare facilities. **As the dissatisfaction about amount of information received during informed consent process was mostly reported from participants interviewed in the university hospital, it may be**

indicated to prioritize improvement actions in this type of facility. It is also recommended to raise awareness among the healthcare providers for not underestimating the female rights of getting enough information during informed consent process and to empower females to seek their rights, as majority of female participant reported they are not receiving enough information. As population expectations evolves with time, it is recommended to repeat and update that type of study which seeks patient opinions about important healthcare related matters such as informed consent process.

### **Abbreviations:**

Not Applicable.

### **Declarations:**

**Ethics approval and consent to participate:** The protocol was approved by the Research and Ethical Committee of the National Research Centre, Egypt, and conduct of the study complied with the International Ethical Guidelines for Biomedical Research Involving Human Subjects [22]. Verbal acceptance to participate was one of the enrolment criteria for the study subjects.

**Consent for publication:** Not applicable

**Availability of data and material:** The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they have no competing interests.

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**Authors' contributions:** AM and HA wrote and submitted the proposal and reviewed overall data analysis and manuscript. HS, SA, MS, WS and RS collected and entered data from study setting 1. RA, HM, AM, GA and AA collected and entered data from study setting 2. HE, HB, DE, MA and AF collected and entered data from study setting 3. HA interpreted the data, wrote and submitted the manuscript. TR and SE analysed the data. EE and AE revised statistical analysis. AS, AH and MS assisted in manuscript revision. All authors read and approved the final manuscript.

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