Cancer is one of the most difficult diseases affecting humans in terms of prognosis, development and treatment, as well as its effects on the community of people around the patient—whether family, friends or colleagues—and its social and economic effects.\(^1\) Cancer is more difficult when it affects children, and in addition to the vulnerability of a child who has not completed his or her mental and cognitive structure, cancer causes more weakness.\(^2\) Vulnerability is not limited to the child with cancer, but is transmitted to the child’s family, especially the parents, who live with the child on a daily basis, see the child's level of maturity rather than having reached a certain age so that they could give assent, while the rest considered the age of 13-14 as a suitable age.

These findings reflect an increasing ethical awareness regarding parental consent and child assent, and they can be formulated in a recommendation for a more ethical practice in the field of childhood cancer and pediatrics in general.

**KEYWORDS**
cancer, children, consent, assent

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\(^1\)Andersen, B.L., Kiecolt-Glaser, J.K., Glaser, R. (1994). A biobehavioral model of cancer stress and disease course. American Psychologist. 49(5):389.

\(^2\)Vrijmoet-Wiersma, C.M., van Klink, J.M., Kolk, A.M., Koopman, H.M., Ball, L.M., Maarten Egeler, R. (2008). Assessment of parental psychological stress in pediatric cancer: A review. Journal of Pediatric Psychology. 19;33(7):694-706.
his or her weakness, walk with the child through the steps of diagnosis and see the consequences of treatment. The parents’ intimate involvement makes them feel like they too are patients and not only their child.\(^5\) Statistics show that childhood cancer is the leading cause of death for children between the ages of 1 and 19 globally,\(^4\) and Saudi statistics show that in 2013 about 845 children with cancer were between the ages of 1 and 14.\(^5\)

Children with cancer usually undergo many tests and procedures to confirm the diagnosis and determine the type and degree of cancer, as well as to follow up on their condition and monitor their improvement and response to the treatments provided.\(^6\) This may include a complete blood count and blood films, various types of x-rays, and taking biopsies from the bone marrow.

The impact of childhood cancer and its difficult treatment is not limited to parents, relatives and the social community, but extends to doctors, nurses and other healthcare providers who have significant interaction with these children with cancer for long periods of time, developing close relationships with the children and their families.\(^7\) The impact is not unilateral but mutual, as doctors and nurses affect the children and their parents, and the children and their parents affect the doctors and nurses. The healthcare providers are affected by the responsibility they feel toward their patients and their patients’ families and their views towards the rights of the child and their families, as well as by the relative social, educational, economic and political conditions of these doctors, nurses and patients.\(^8\)

In recent decades, concepts of bioethics have evolved and become widely accepted and applied in clinical practice around the world. At the forefront of these ethical principles is the principle of patient independence and informed consent, which is the cornerstone of respect and appreciation of human dignity.\(^9\) However, patient independence and informed consent faces a real dilemma when the person is unable to exercise his or her rights because of the ambiguity or inability to understand the medical situation in its various dimensions, the inability to consider and balance the options available, or the inability to make appropriate decisions. All of these situations exist in the case of children with cancer, which makes the issue of consent a sensitive issue for applied ethics that calls for solutions that ensure access to the best options that respect the child and his or her parents, taking into account the child’s interest as an absolute priority in any diagnostic, therapeutic or research decision.

The situation is further complicated in childhood cancer, where aggressive treatment is often used, with a need to balance the pros and cons of treatment and the need to make a decision quickly. Moreover, the ability to distinguish between treatment plans and research protocols is crucial to making sound ethical decisions based on knowledge and independence.\(^10\)

Instead of rigidly focusing on absolute parental consent, as was the case over long periods of the history of informed consent, the current trend is to promote the autonomy of children and encourage them to exercise freedom of choice and create the right conditions for them to exercise this right. Although this seems simple, it is not: knowing when a child has the ability to make an informed decision and understand information may not be easy at all, especially given the different environments, genesis, methods of education and genetic factors that play a crucial role in how mental capacity develops.\(^11\)

Determining the amount of information that should be provided to a child with cancer and his or her parents is another complex matter: is it better to provide only a little information that is more likely to be read and understood, or should we provide detailed information and then leave the child and his or her parents free to read what they want, knowing that the possibility of them reading the full approval text is very low. The concern about the size of the consent document is especially great with lengthy documents prepared by pharmaceutical companies for medical trials; such documents may be written in a highly legal style to protect the company’s interest, rather than in the child’s best interest and understanding.\(^12\)

Hence, this study aims to shed light on some of the ethical challenges surrounding the process of obtaining consent in the field of pediatric cancer by discussing three controversial topics: the consent of one or both parents for the purpose of medical treatment or medical research, the consent (assent) of the child according to age versus level of maturity, and the amount of information that should be included to obtain parental consent or child assent.

### 2 | METHODOLOGY

The study was designed to investigate the views of a random sample of healthcare providers and the parents of patients at the King Abdulaziz Medical City, Riyadh, Saudi Arabia. The topic was ethical challenges in the care of children with cancer, in oncology.

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\(^{3}\)Saudi Cancer Registry. (2013). Cancer Incidence Report Saudi Arabia 2013. www.chs.gov.sa/En/HealthRecords/CancerRegistry/Pages/CancerRegistryRecords.aspx

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\(^{6}\)Hockenberry-Eaton, M., Diloro, C., Kemp, V. (1995). The relationship of illness longevity and relapse with self-perception, cancer stressors, anxiety, and coping strategies in children with cancer. Journal of Pediatric Oncology Nursing. 12(2):71-9.

\(^{7}\)Ademola-Bello, B. (2010). Dignity and informed consent in the treatment of mature minors. Journal International de Bioéthique. 21(4):103-22, 164-5.

\(^{8}\)Brody, H., Miller, F.G. (2013). The research-clinical practice distinction, learning health systems, and relationships. Hastings Center Report. 43(5):41-7.

\(^{9}\)Unguru, Y., Coppes, M.J., Kamarí, N. (2008). Rethinking pediatric assent: from requirement to ideal. Pediatric Clinics of North America. 1:55(1):211-22.

\(^{10}\)Sprigg, M. (2010). Understanding consent in research involving children: The ethical issues. A handbook for human research ethics committees and researchers. Melbourne: Children’s Bioethics Centre.
departments in hospitals in Saudi Arabia. The study comprised four different groups, each with 100 participants including physicians, nurses, medical students and parents of children with cancer. Both the physicians and nurses were working in King Fahad Hospital, National Guard, in three different cities: Dammam, Riyadh and Jeddah; and the parent group consisted of parents of children with cancer who were treated in the same three hospitals. The medical students attended King Saud bin Abdulaziz University for Health Sciences. The total number of respondents who agreed to participate was 400.

The survey questions were reviewed by several experts, and Cronbach’s alpha was used to assure reliability and validity. Moreover, a pilot study was done involving five subjects before starting data collection for the main study. Survey questions were written in English for use in three groups: physicians, nurses and medical students; while a translated Arabic version was used in the parents’ group after it had been validated. Four trained research coordinators and one medical student collected the questionnaires. After verbal consent, all respondents completed the questionnaires by themselves, except for the parents’ survey, when interview-based questionnaires were used.

2.1 | Data management and analysis

Data analysis was conducted using SPSS, Version 25 (NY, USA). Categorical data of participants’ characteristics were illustrated in frequencies and percentages, whereas the two study outcomes were presented in means (± Standard deviation). Normally distributed outcomes were statistically tested using student’s t-test and one-way analysis of variance (ANOVA), while categorical outcomes were tested using Pearson’s chi-square. For all statistical analyses, a P-value <0.05 was considered to be significant.

3 | RESULTS

3.1 | Participants’ characteristics

The total number of participants who agreed to enroll in this study was 400 participants, divided into four different groups of 100 each. One hundred participants were recruited for each of the four main study groups (physicians, medical students, nurses and patient’s families/legal guardians). The male to female ratio of the whole sample was 1:1.6, with a mean (±SD) age of 34.3 (10.3) years. Saudi nationals (locals in this setting) comprised 69% (n=276) of the sample, while the others were of various nationalities (expatriates). Participants who were followers of the Islam faith tradition were 337 (84.3%), followers of the Christian faith tradition 54 (13.4%) and followers of other faith traditions 9 (2.3%). More than half of the participants were married (n=221, 55.3%), and the majority (n=294, 73.5%) possessed at least a diploma/college educational degree. Other sample characteristics are listed in Table 1.

3.2 | Who shall approve the consent for medical treatment and research?

When asked about which of the two parents should give consent for medical treatment of a child with cancer, half of the participants reported that both parents should give consent, and 42.0% believed that either of them may sign. For medical research studies, more than half acknowledged that both parents should sign, followed by one-third who stated that either of them may sign. A small percentage of participants responded that the sole authority to give parental consent for treatment or research should reside with fathers (6.8% and 7.3%, respectively), and a similarly small percentage (1.3% and 1.5%, respectively) responded that only mothers should have the authority to give parental consent (see Table 2).

The participants’ preferences on who shall approve the consent for medical treatment and medical research showed many differences, as described in Tables 3 and 4. Younger participants and females were in favor of both parents or either of them, with no difference for consent in treatment purposes and research purposes, both compared to their
TABLE 2  Sample’s preferences on who shall approve the consent for medical treatment versus medical research.

|                           | Father only n (%) | Mother only n (%) | Any available parent n (%) | Both parents together n (%) |
|---------------------------|-------------------|-------------------|-----------------------------|-----------------------------|
| Which parent should give consent for medical treatment of child with cancer | 27 (6.8%)         | 5 (1.3%)          | 168 (42.0%)                 | 199 (49.6%)                 |
| Which parent should give a consent for medical Research of child with cancer | 29 (7.3%)         | 6 (1.5%)          | 137 (34.3%)                 | 226 (56.5%)                 |

n: frequency, %: percentage

TABLE 3  Sample’s preferences on who shall approve the consent for treatment across sample characteristics.

|                           | Father only n (%) | Mother only n (%) | Any available parent n (%) | Both parents together n (%) |
|---------------------------|-------------------|-------------------|-----------------------------|-----------------------------|
| Age (years)               |                   |                   |                             |                             |
| ≤39                       | 11 (3.9%)         | 3 (1.1%)          | 116 (41.4%)                 | 150 (53.6%)                 |
| >39                       | 16 (13.3%)        | 2 (1.7%)          | 43 (43.8%)                  | 40 (41.3%)                  |
| P=0.003                   |                   |                   |                             |                             |
| Sex                       |                   |                   |                             |                             |
| Male                      | 18 (11.8%)        | 2 (1.3%)          | 64 (41.8%)                  | 71 (45.1%)                  |
| Female                    | 9 (3.4%)          | 3 (1.2%)          | 104 (42.1%)                 | 130 (52.6%)                 |
| P=0.027                   |                   |                   |                             |                             |
| Nationality               |                   |                   |                             |                             |
| Saudi                     | 19 (6.9%)         | 2 (0.7%)          | 119 (43.3%)                 | 135 (49.1%)                 |
| Non Saudi                 | 8 (6.5%)          | 3 (2.4%)          | 48 (38.7%)                  | 64 (51.6%)                  |
| P=0.0316                  |                   |                   |                             |                             |
| Religion                  |                   |                   |                             |                             |
| Muslim                    | 23 (6.8%)         | 3 (0.9%)          | 147 (43.6%)                 | 164 (48.7%)                 |
| Non-Muslim                | 4 (6.3%)          | 2 (3.2%)          | 21 (33.3%)                  | 36 (57.1%)                  |
| P=0.051                   |                   |                   |                             |                             |
| Marital status            |                   |                   |                             |                             |
| Single                    | 21 (9.5%)         | 4 (1.8%)          | 94 (42.5%)                  | 101 (45.7%)                 |
| Married                   | 3 (1.9%)          | 1 (0.6%)          | 69 (43.1%)                  | 87 (54.4%)                  |
| Divorced                  | 2 (25.0%)         | 0 (0.0%)          | 2 (25.0%)                   | 4 (50.0%)                   |
| Widow                     | 1 (11.1%)         | 0 (0.0%)          | 3 (33.3%)                   | 5 (55.6%)                   |
| P=0.167                   |                   |                   |                             |                             |
| Current Job               |                   |                   |                             |                             |
| Physician                 | 1 (1.0%)          | 1 (1.0%)          | 55 (55.0%)                  | 43 (43.0%)                  |
| Medical Student           | 3 (3.0%)          | 0 (0.0%)          | 41 (41.0%)                  | 56 (56.0%)                  |
| Nurse                     | 3 (3.0%)          | 3 (3.0%)          | 38 (38.0%)                  | 56 (56.0%)                  |
| Patient’s family          | 20 (20.0%)        | 1 (1.0%)          | 34 (34.0%)                  | 45 (45.0%)                  |
| P=0.000                   |                   |                   |                             |                             |
| Education                 |                   |                   |                             |                             |
| Undergraduate             | 13 (30.2%)        | 1 (2.3%)          | 13 (30.2%)                  | 16 (37.2%)                  |
| Bachelor                  | 10 (3.4%)         | 4 (1.4%)          | 122 (41.4%)                 | 158 (53.6%)                 |
| Postgraduate              | 4 (6.5%)          | 0 (0.0%)          | 33 (53.2%)                  | 25 (40.3%)                  |
| P=0.000                   |                   |                   |                             |                             |

n: frequency, %: percentage

counter groups. Moreover, both younger and female participants had less preference for limiting the right of consent to fathers only, and even less for limiting the right to mothers only. The categories of non-Saudis and non-Muslims, which overlapped, and nurses favored the involvement of both parents in consenting for medical treatment and medical research. The same
preferences were observed by the categories of married participants and those with diploma/bachelor degrees. Medical students and nurses showed preference for having both parents available to sign the consent in medical treatments, whereas physicians showed the highest preference in having either parent available for signing the consent in medical research.

### 3.3 Child's age to provide assent for medical treatment and medical research

Analyses were conducted to determine whether the study participants were in favor of a specific age for children or in favor of the child reaching a personal level of maturity in order for the child to provide assent for treatment and research.

Around one-quarter of participants stated that with parental consent, children with cancer can give assent if the child reaches a certain age, which was 13.1 ± 3.4 years for medical treatment and 14.1 ± 3.9 years for medical research. The other three-quarters of participants responded that child assent for both treatment and research could be obtained regardless of the age when the child reaches maturity (see Table 5).

There were no statistically significant differences between participants who favored age-specific and personal maturity-specific criteria for children to provide assent for either medical treatment or medical research (see Table 6). However, the mean age differed

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### Table 4: Sample's preferences on who shall approve the consent for research across sample characteristics.

|                      | Father only n (%) | Mother only n (%) | Any available parent n (%) | Both parents n (%) |
|----------------------|-------------------|-------------------|----------------------------|-------------------|
| **Age (years)**      |                   |                   |                            |                   |
| ≤39                  | 10 (3.6%)         | 4 (1.4%)          | 103 (36.8%)                | 163 (58.2%)       |
| >39                  | 19 (15.8%)        | 2 (1.7%)          | 34 (28.3%)                 | 63 (52.5%)        |
| **P**                | 0.000             |                   |                            |                   |
| **Sex**              |                   |                   |                            |                   |
| Male                 | 20 (13.1%)        | 1 (0.7%)          | 50 (41.6%)                 | 81 (52.9%)        |
| Female               | 9 (3.6%)          | 5 (2.0%)          | 87 (35.2%)                 | 145 (58.7%)       |
| **P**                | 0.009             |                   |                            |                   |
| **Nationality**      |                   |                   |                            |                   |
| Saudi                | 23 (8.4%)         | 4 (1.5%)          | 96 (34.9%)                 | 151 (54.9%)       |
| Non Saudi            | 6 (4.8%)          | 2 (1.6%)          | 40 (32.3%)                 | 75 (60.5%)        |
| **P**                | 0.653             |                   |                            |                   |
| **Religion**         |                   |                   |                            |                   |
| Muslim               | 23 (7.7%)         | 3 (1.2%)          | 119 (35.3%)                | 187 (55.5%)       |
| Non-Muslim           | 3 (4.8%)          | 2 (3.2%)          | 18 (28.6%)                 | 39 (61.9%)        |
| **P**                | 0.298             |                   |                            |                   |
| **Marital status**   |                   |                   |                            |                   |
| Single               | 24 (0.9%)         | 5 (2.3%)          | 73 (33.0%)                 | 118 (53.4%)       |
| Married              | 2 (1.3%)          | 1 (0.6%)          | 60 (37.5%)                 | 97 (60.6%)        |
| Divorced             | 1 (12.5%)         | 0 (0.0%)          | 3 (37.5%)                  | 3 (37.5%)         |
| Widow                | 2 (22.2%)         | 0 (0.0%)          | 1 (11.1%)                  | 6 (66.7%)         |
| **P**                | 0.000             |                   |                            |                   |
| **Current job**      |                   |                   |                            |                   |
| Physician            | 1 (1.0%)          | 1 (1.0%)          | 45 (45.0%)                 | 53 (53.0%)        |
| Medical Student      | 2 (2.0%)          | 0 (0.0%)          | 32 (32.0%)                 | 66 (66.0%)        |
| Nurse                | 2 (2.0%)          | 3 (3.0%)          | 34 (34.0%)                 | 60 (60.0%)        |
| Patient's family     | 24 (24.0%)        | 2 (2.0%)          | 26 (26.0%)                 | 47 (47.0%)        |
| **P**                | 0.000             |                   |                            |                   |
| **Education**        |                   |                   |                            |                   |
| Undergraduate        | 16 (37.2%)        | 2 (4.7%)          | 8 (18.6%)                  | 17 (39.5%)        |
| Bachelor             | 11 (3.7%)         | 4 (1.4%)          | 105 (35.6%)                | 173 (58.6%)       |
| Postgraduate         | 2 (3.2%)          | 0 (0.0%)          | 24 (38.7%)                 | 36 (58.1%)        |
| **P**                | 0.000             |                   |                            |                   |

n: frequency, %: percentage
TABLE 5  Samples’ perception of the suitable child’s age specific versus maturity specific to provide assent for treatment and research

| Age specific | Maturity specific |
|--------------|-------------------|
| Mean ± SD (n; %) | Mean ± SD (n; %) |

| Characteristics | Treatment | Research |
|-----------------|-----------|----------|
| Age (years)     |           |          |
| ≤39             | 103 (25.8%) | 297 (74.3%) |
| >39             | 104 (26%)  | 296 (74%)  |

| Sex            |           |          |
|----------------|-----------|----------|
| Male           | 109 (71.2%) | 188 (76.1%) |
| Female         | 44 (28.8%)  | 59 (23.9%)  |

| Nationality    |           |          |
|----------------|-----------|----------|
| Saudi          | 202 (73.5%) | 73 (26.5%) |
| Non Saudi      | 95 (76.6%)  | 29 (23.4%)  |

| Religion       |           |          |
|----------------|-----------|----------|
| Muslim         | 248 (73.6%) | 89 (26.4%) |
| Non-Muslim     | 49 (77.8%)  | 14 (22.2%)  |

| Marital status |           |          |
|----------------|-----------|----------|
| Single         | 170 (76.9%) | 51 (23.1%) |
| Married        | 111 (69.4%) | 49 (30.6%) |
| Divorced       | 8 (100.0%)  | 0 (0.0%)  |
| Widow          | 6 (66.7%)   | 3 (33.3%) |

| Current job    |           |          |
|----------------|-----------|----------|
| Physician      | 74 (74.0%) | 26 (26.0%) |
| Medical Student| 69 (69.0%) | 31 (31.0%) |
| Nurse          | 79 (79.0%) | 21 (21.0%) |
| Patient’s family| 75 (74.0%) | 25 (26.0%) |

| Education      |           |          |
|----------------|-----------|----------|
| Undergraduate  | 34 (79.1%) | 9 (20.9%) |
| Bachelor       | 216 (73.2%) | 79 (26.8%) |
| Postgraduate   | 47 (75.8%)  | 15 (24.2%) |

n: frequency, %: percentage, SD Standard deviation

TABLE 6  Samples’ preferences of the suitable child’s age specific versus maturity to provide assent for medical treatment and medical research across sample characteristics

3.4  Size of the consent and assent forms

The various categories of participants expressed preferences regarding the nature of the consent form (size and content). Regarding consent for treatments, more than half of participants according to different characteristics. Older, male, non-Saudi, non-Muslim, physicians and nurses favored lower age compared with counter groups (see Table 7).
TABLE 7 Samples’ preferences of the suitable child’s age specific to provide assent for treatment and research across sample characteristics

| In age specific, the age which children with cancer can give assent for | Treatment (Mean ±SD) | Research (Mean ±SD) |
|---|---|---|
| Age (years) | | |
| ≤39 | 13.6±3.5 | 14.5±3.1 |
| >39 | 12.1±3 | 13.0±2.9 |
| P=0.000 | P=0.000 | |
| Sex | | |
| Male | 13.2±3.6 | 13.9±3.3 |
| Female | 16.7±3.25 | 14.2±3 |
| P=0.757 | P=0.381 | |
| Nationality | | |
| Saudi | 13.8±3.5 | 14.6±3.2 |
| Non Saudi | 11.8±3.7 | 13.1±2.7 |
| P=0.000* | P=0.000* | |
| Religion | | |
| Muslim | 13.5±3.5 | 14.4±3.1 |
| Non-Muslim | 11.7±3.1 | 14.1±3.1 |
| P=0.000* | P=0.000* | |
| Marital status | | |
| Single | 12.5±3.2 | 13.7±3.0 |
| Married | 14.2±3.4 | 14.7±3.1 |
| Divorced | | |
| Widow | | |
| P=0.022* | P=0.202 | |
| Current job | | |
| Physician | 11.5±2.7 | 12.5±2.5 |
| Medical Student | 15.8±2.7 | 16±2.7 |
| Nurse | 11.9±2.9 | 13.3±2.7 |
| Patient’s family | 13.5±3.4 | 15±3.3 |
| P=0.243 | P=0.009 | |
| Education | | |
| Undergraduate | 13.2±3.4 | 14.4±3.3 |
| Bachelor | 13.4±3.5 | 14.4±3.0 |
| Postgraduate | 12.0±3.7 | 12.5±2.7 |
| P=0.062 | P=0.002 | |

SD: standard deviation, P= P-value, * = statistically significant at <0.05,

When asked about the characteristics of adult consent for medical treatments, non-Saudis (65.3%), non-Muslims (74.6%), single (57.9%), nurses (71.0%), and those with diploma/bachelor degrees (59.3%) all showed significantly higher preference for detailed consent forms (Table 9).

Regarding adult consent documents for medical research, non-Muslims (69.8%), non-Saudis (60.5%) and nurses (66.0%) were all significantly in favor of a detailed version (Table 10).

Patients’ families preferred a shorter version of child assent forms for treatment and for research (88.0% and 80.0%, respectively). The exception was that, in terms of level of education, bachelor degree holders preferred detailed assent forms for treatment; no significant difference was found among various other characteristics (Tables 9 & 10).

4 | DISCUSSION

This study contains results from different groups, but related to people with some relationship with children with cancer. The group consisting of doctors, who lead the medical teams and are responsible for developing treatment plans and making therapeutic decisions and diagnostic procedures, often build on their experience, and do so in accordance with global protocols based on proven research and studies. The group consisting of nurses who take care of children hour after hour and, as a result of the length of medical care, develop privileged relationships with children with cancer. As a result, nurses are fully aware of the abilities, obsessions and desires of these children. Moreover, the nurses in this study were the most diverse group compared to the other study groups in terms of nationality and religion, as most of them were non-Saudis and non-Muslims; their diversity may have contributed to their responses in addition to their professional identity as nurses. The group of parents is a unique group who live with the pain and hopes of their sick child, sharing with them the moments of illness and healing. Based on their understanding of their child’s best interests, they have to decide whether to accept or reject treatment and diagnostic plans. The medical students are the group whose experiences were not yet complete and who have not been under psychological and medical pressure to confront children with cancer; therefore, among the four groups they come closest to representing the public view.

However, despite the wide variety and different relationships of the participants with children with cancer in this study, their responses did not show significant differences. Indeed, a high degree of similarity was observed, giving an impression of holding common views of the three problematic issues discussed in this paper, namely; which parents must give informed consent; what criteria should be used to enable the child to give assent; and what is the appropriate size of the consent form used to obtain parental consent and child assent.
| Table 8 | Samples’ perception to the characteristics of consent and assent for both treatment and research. |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------|
| **Short form** (contains only the important | **Medium form** (contains important issues and some details) | **Detailed form** (contains detailed information) |
| Information) n (%)                             | n (%)                                                                                            | n (%)                                                                                            |
| Parental Consent form for treatment           | 32 (8%)                                                                                         | 147 (36.8%)                                                                                     | 221 (55.3%)                                                                                           |
| Parental Consent form for research            | 54 (13.5%)                                                                                     | 136 (34.0%)                                                                                     | 208 (52%)                                                                                             |
| Child Assent form for treatment               | 294 (73.5%)                                                                                    | 73 (18.3%)                                                                                      | 33 (8.3%)                                                                                             |
| Child Assent form for research                | 285 (71.3%)                                                                                    | 88 (22%)                                                                                        | 26 (6.5%)                                                                                             |

n: frequency, %: percentage

| Table 9 | Samples’ preferences towards the characteristics of consent and assent for treatment purposes across sample characteristics. |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------|
| **Consent (by parents) for treatment**        | **Consent (by parents) for research**                                                                                   |
| Short n (%) Medium n (%) Detailed n (%)       | Short n (%) Medium n (%) Detailed n (%)                                                                                   |
| **Age (years)**                               |                                                                                                                              |
| ≤39                                           |                                                                                                                              |
| >39                                           |                                                                                                                              |
| P=0.725                                       | P=0.722                                                                                                                     |
| **Sex**                                       |                                                                                                                              |
| Male                                          |                                                                                                                              |
| Female                                        |                                                                                                                              |
| P=0.038                                       | P=0.479                                                                                                                     |
| **Nationality**                               |                                                                                                                              |
| Saudi                                         |                                                                                                                              |
| Non Saudi                                     |                                                                                                                              |
| P=0.024                                       | P=0.049                                                                                                                     |
| **Religion**                                  |                                                                                                                              |
| Muslim                                        |                                                                                                                              |
| Non-Muslim                                    |                                                                                                                              |
| 0.003                                         | 0.008                                                                                                                        |
| **Marital status**                            |                                                                                                                              |
| Single                                        |                                                                                                                              |
| Married                                       |                                                                                                                              |
| Divorced                                      |                                                                                                                              |
| Widow                                         |                                                                                                                              |
| P=0.005                                       | P=0.001                                                                                                                     |
| **Current job**                               |                                                                                                                              |
| Physician                                     |                                                                                                                              |
| Medical Student                               |                                                                                                                              |
| Nurse                                         |                                                                                                                              |
| Patient’s family                              |                                                                                                                              |
| P=0.001                                       | P=0.035                                                                                                                     |
| **Education**                                 |                                                                                                                              |
| Undergraduate Bachelor                        |                                                                                                                              |
| Postgraduate                                  |                                                                                                                              |
| 0.001                                         | 0.022                                                                                                                        |

n: frequency, %: percentage, P= P-value, *=statistically significant at <0.05.
TABLE 10  Samples’ preferences towards the characteristics of consent and assent for research purposes across sample characteristics.

|                        | Assent (of the Child) for treatment | Assent (of the Child) for research |
|------------------------|-------------------------------------|------------------------------------|
|                        | Short n (%)       | Medium n (%)      | Very detailed | Short n (%)       | Medium n (%)      | Very detailed |
| Age (years)            |                     |                     |               |                     |                     |               |
| ≤39                    | 209 (74.6%)        | 46 (16.4%)         | 25 (8.9%)     | 201 (71.8%)        | 63 (22.5%)         | 16 (5.7%)     |
| >39                    | 85 (70.8%)         | 27 (22.5%)         | 8 (6.7%)      | 85 (70.8%)         | 25 (20.8%)         | 10 (8.3%)     |
| P=0.003                |                     |                     |               | P=0.606            |                     |               |
| Sex                    |                     |                     |               |                     |                     |               |
| Male                   | 114 (74.5%)        | 26 (17.0%)         | 13 (8.5%)     | 107 (69.9%)        | 38 (24.8%)         | 8 (5.2%)      |
| Female                 | 180 (72.9%)        | 47 (19.0%)         | 20 (8.1%)     | 179 (72.5%)        | 0 (20.2%)          | 18 (7.3%)     |
| P=0.875                |                     |                     |               | P=0.448            |                     |               |
| Nationality            |                     |                     |               |                     |                     |               |
| Saudi                  | 207 (75.3%)        | 49 (17.8%)         | 19 (6.9%)     | 196 (71.3%)        | 65 (23.6%)         | 14 (5.1%)     |
| Non Saudi              | 86 (69.4%)         | 24 (19.4%)         | 14 (11.3%)    | 89 (71.8%)         | 23 (18.5%)         | 12 (9.7%)     |
| P=0.286                |                     |                     |               | P=0.152            |                     |               |
| Religion               |                     |                     |               |                     |                     |               |
| Muslim                 | 254 (75.4%)        | 59 (17.5%)         | 24 (7.1%)     | 242 (71.8%)        | 76 (22.6%)         | 19 (5.6%)     |
| Non-Muslim             | 40 (63.5%)         | 14 (22.2%)         | 9 (14.3%)     | 44 (69.8%)         | 12 (19.0%)         | 7 (11.1%)     |
| P=0.083                |                     |                     |               | P=0.250            |                     |               |
| Marital status         |                     |                     |               |                     |                     |               |
| Single                 | 177 (80.1%)        | 32 (14.5%)         | 12 (5.4%)     | 165 (74.7%)        | 40 (18.1%)         | 16 (7.2%)     |
| Married                | 107 (66.9%)        | 35 (21.9%)         | 18 (11.3%)    | 108 (67.5%)        | 43 (26.9%)         | 9 (5.6%)      |
| Divorced               | 6 (75.0%)          | 2 (25.0%)          | 0 (0.0%)      | 6 (75.0%)          | 2 (25.0%)          | 0 (0.0%)      |
| Widow                  | 2 (22.2%)          | 4 (44.4%)          | 3 (33.3%)     | 5 (55.6%)          | 3 (33.3%)          | 1 (11.1%)     |
| P=0.001                |                     |                     |               | P=0.426            |                     |               |
| Current job            |                     |                     |               |                     |                     |               |
| Physician              | 72 (72.0%)         | 19 (19.0%)         | 9 (9.0%)      | 67 (67.0%)         | 24 (24.0%)         | 9 (9.0%)      |
| Medical student        | 67 (67.0%)         | 24 (24.0%)         | 9 (9.0%)      | 65 (65.0%)         | 32 (32.0%)         | 3 (3.0%)      |
| Nurse                  | 67 (67.0%)         | 20 (20.0%)         | 13 (13.0%)    | 74 (74.0%)         | 16 (16.0%)         | 10 (10.0%)    |
| Patient’s family       | 88 (88.0%)         | 10 (10.0%)         | 2 (2.0%)      | 80 (80.0%)         | 16 (16.0%)         | 4 (4.0%)      |
| P=0.008                |                     |                     |               | P=0.051            |                     |               |
| Education              |                     |                     |               |                     |                     |               |
| Undergraduate          | 39 (90.7%)         | 3 (7.0%)           | 1 (2.3%)      | 33 (76.7%)         | 9 (20.9%)          | 1 (2.3%)      |
| Bachelor               | 204 (69.2%)        | 61 (20.7%)         | 30 (10.2%)    | 207 (70.2%)        | 66 (22.4%)         | 22 (5.5%)     |
| Postgraduate           | 51 (82.3%)         | 9 (14.5%)          | 2 (3.2%)      | 46 (74.2%)         | 13 (21.0%)         | 3 (0.8%)      |
| P=0.013                |                     |                     |               | P=0.698            |                     |               |

n: frequency, %: percentage, P= P-value, *=statistically significant at <0.05.

4.1  Father or mother, who should give consent?

It is widely accepted that before any medical procedure, treatment or research, informed consent must be obtained from the guardian, who is often a parent, as stipulated by international standards such as the Helsinki Declaration,13 international guidelines for research ethics,14 local medical research ethics law, and other national laws in different countries.15 Parental consent is also consistent with fatwas

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13 World Medical Association. (2008). Declaration of Helsinki. Ethical principles for medical research involving human subjects. http://www.wma.net/e/policy/b3.htm.
14 Council for International Organizations of Medical Sciences. (2002). International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva: CIOMS.
15 Alahmad, G. (2017). The Saudi Law of Ethics of Research on Living Creatures and its Implementing regulations. Developing World Bioethics. 17(2):63-9.
on Islamic jurisprudence councils, and medical organizations, as well as the writings of local and international authors. However, none of the international, Islamic and local guidelines provide criteria about which parent should provide (or be given the priority to provide) informed consent for sick children who need medical intervention. An institutional document (where this study was conducted) gives the father priority, and then the grandfather, before the mother is given the right to provide consent. This order may be adapted from the order that is used in Islamic jurisprudence in non-medical aspects.

However, the findings of this study, which support both parents or either parent having the right to consent to their child undergoing any medical treatment procedure and/or participation in medical research, is contrary to the traditional way of thinking that gives fathers priority or an exclusive right against mothers when it comes to consent. The results were clearly closer to the equality of fathers and mothers’ approach. The largest percentage of participants favor obtaining consent from both parents together, as opposed to from only one of them. This is true not only for the participants overall, but also for each group independently. This was followed by a preference for choosing any available parent. In contrast, the percentage that preferred to limit consent to either fathers or mothers was very low; in fact the percentage favoring fathers (6.8% for treatment and 7.3% for research) as the sole consenters was slightly higher than the percentage that favored mothers (1.3% for treatment and 1.5% for research). These results were similar for medical treatment and medical research, suggesting that this trend truly reflects their opinions.

A transition from absolute parenthood rights for the father to shared decisions without distinguishing between the two parents can signify a shift towards gender equality, especially in a society where parenthood is part of its history. However, this conclusion may not be accurate, as there may be other reasons to consider, such as fear for the sick child, fear of taking responsibility for decisions, and the desire that the decision taken be appropriately consultative and taken by both parents. The choice of either parent can be explained by the unavailability or absence of one of them, considering most fathers work during the day while mothers often stay with their children in the hospital, (despite the significant increase in the proportion of working women in the workforce in recent years); or even because of the separation of parents.

4.2 Child assent: according to age or level of maturity

Ethicists have often debated the age at which a child is able to give medical consent on his or her own without paying attention to his parents’ consent. Reaching the age of 18 years or more is widely accepted worldwide as the age of consent, regardless of the legal or logical basis used to determine this recognition. Here, a moral question arises about the right of children under 18 years of age to express their opinion, even if their opinion does not have ultimate power and authority. Then, does this right include all children under 18, regardless of their age or degree of development? It is difficult to determine when a child can accept or reject any medical procedure and when a child can be expected to understand the information provided to him or her. Moreover, should the criterion be set at a specific age or take into account other factors of developmental maturity?

When the sample participants were asked regarding the age versus personal level of maturity of a child in determining the ability to give assent, a clear statistical difference was found about 75% of participants preferred level of maturity, compared with a minority who preferred age. No statistically significant differences were noted among the participants for preferences of maturity (see Table 6 above). However, differences were noted among the participants for preferences for the age a child could give assent for treatment and for research participation (see Table 7 above).

Consistent for either medical treatment assent and medical research assent was the fact that physicians and nurses accepted the lowest ages. This can be explained by the fact that as healthcare providers, both physicians and nurses have extensive and lengthy experience dealing with large numbers of children with cancer, and as a result, they have a better, more realistic view of a child’s ability to participate in decision-making and to give assent. Their experience with childhood cancer enables them to allow children at the youngest ages to give assent. They know the disease and the age group’s ability (in this context) better than the other groups; hence they select the lowest ages allowable for assent.

4.3 Size of consent or assent forms

The next topic reviewed by the study participants was the extent and size of parental consent documents, which usually includes all aspects required to obtain approval, a treatment plan, side effects, complications, risks, benefits, and alternative treatments and their risks and benefits. Hence, the participants were asked whether the parents should be given short consent forms that include only the basic information and elements that achieve accepted ethical
standards, medium length approval forms that include important issues and some details, or longer approval forms that include very detailed information—this last option of informed consent being usually provided by pharmaceutical companies who provide funding. The influence of the pharmaceutical industry (Fourth Report for Session 2004–5). London: The Stationary Office Ltd. Retrieved February 15, 2020, from http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhthlth/42/4202.htm.

Parents expressed the least preference for a short consent form among the three options, followed by the medium length consent form, while more than half of the participants preferred the lengthy detailed consent form. This reflects the parents’ desire to comprehend every detail they can about the medical treatment before giving their consent. This is to be expected due to the fact that many of the participants were married, and also a large proportion were over 39 years old. Parents want to take care of their child as part of a sense of responsibility towards their child and want to limit the amount of information a child faces to ensure the child is not overwhelmed.

Results regarding having children involved in medical research closely reflected those related to medical treatment, which confirms that participants expect the same level of attention and care from parents who agree to medical research as is the case in medical treatment.

At the same time, it cannot be overlooked that the desire for the provision of detailed consent documents does not necessarily mean that those who provide consent will actually read the documents in full, as studies of adult patients have shown that they read shorter approval documents at a higher rate than when these approval documents are long. Some researchers have noted that the size of consent documents is increasing in research related to cancer. The more detailed approval documents may be less appreciated by parents, as a large part of these details may not be important to them or to their child’s interest. Long, detailed consent forms often include extensive information related to legal and financial aspects that may not be useful in achieving the goal of informed consent. In fact, such details often aim to provide legal protection for companies and researchers rather than provide greater knowledge to patients, and therefore it cannot be claimed that they are necessarily in their child’s best interest.

By contrast, 73.5% of the participants felt that the child’s assent for medical treatment should involve a short approval form to help the child make a decision, while the rest preferred the use of a medium or detailed form for approval. These numbers make sense, since most of the participants, given their medical background, realize that most children can understand the treatment protocol to give consent in a short, easy-to-read explanation without raising their anxiety. The use of age-appropriate consent forms would make collaboration with children more acceptable, while use of the medium and detailed explanations may be beyond the child’s comprehension and attention span, and unnecessary, especially since parental consent is crucial and most important in allowing any medical procedure. Hence, there is no need to overburden the child with the same standards required for obtaining parental consent.

The same applies to the assent of the child for participation in medical research as for assent to medical treatment because they are considered similar regarding the amount of information that must be provided in the child’s assent forms.

While there was an acceptable balance between subgroups, it was noted that mothers tend more often than fathers to prefer more detailed approvals. Nurses were more likely to use detailed parental consent forms in both medical treatment or medical research, and the reason for this may be their preference to obtain full and genuine consent from both the parents. Because of their long and direct relationship and daily conversations with parents, nurses are better equipped to understand the feelings of parents and to estimate their need for greater detail.

5 Limitations

Our study had a number of limitations: first, given the relatively small sample size for a large country such as Saudi Arabia, studies of larger samples, from other regions, may be necessary to obtain a clearer picture; second, a self-administration style of questionnaire was used for the groups of physicians, nurses and medical students, while the group of patients’ families was assisted by the study coordinators and they may have been affected by their explanations.

6 Conclusion

This paper will help to clarify some difficult points, in order to develop more realistic expectations for parental consent and children’s assent in the field of pediatric cancer.

Despite the wide variety of participants in this study, which was intended to provide a deep understanding of the concept of parental consent and child assent in pediatric oncology, we note that there are only a limited number of differences between these participants. The feeling of maximizing the best interest of a child with cancer was the main impetus behind the opinions expressed by the participants, especially since this group of young patients is a very vulnerable group and in urgent need of protection.

The findings clearly indicates an approach to equality between fathers and mothers, with a large proportion of participants preferring, despite their different backgrounds and functions, to obtain consent from both parents together, followed by consent from either parent, while the percentage of participants that expressed preference for limiting parental consent to fathers was very low.
This was true for consent for both medical treatment and medical research. This is not just a philosophical change of thinking, and it offers better protection to children with cancer.

With regard to the information provided for obtaining the child’s assent, the participants expressed a preference for providing children with an amount and type of information that could be understood by the child and allow the child to give valid assent. For parental consent there was preference for more information to enable them to be informed of their child’s illness, while a smaller percentage of respondents preferred less information, relying on their trust in the decisions made by treating doctors and medical researchers.

The majority of participants thought that the child’s ability to give assent was related more to the degree of development than to his or her age; while others thought that the child reaches this ability by 13-14 years of age, an age that appears to be higher than the age suggested by some guidelines such as good medical practice (GCP). This may be because parents feel the need to protect younger children from exposure to the pressures of obtaining consent. It may be useful to conduct future studies involving direct surveys of children.

The results of this study may not reflect the general view of society, but the results undoubtedly offer a vision that may indicate that the absolute patriarchal vision is decreasing and the sense of the independence of children is increasing. Looking ahead, our findings could be formulated in recommendations for more ethical practices in Saudi Arabia and the Middle East that respect the child’s dignity and best interests, in the field of childhood cancer and pediatrics in general.

Author Contributions

Ghiath Alahmad designed, directed, analyzed and interpreted the study data and he was the major contributor in writing the manuscript. Hala Alkamli, Muneera AlSaqabi and Mona Aleidan helped in collecting questionnaires, participated in data analysis, and helped in drafting the manuscript. All authors have read and approved the manuscript.

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