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An Interdisciplinary Approach to the Informed Consent Process: Factors that Affect Participants' Perceptions of the Informed Consent

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Abstract

Participant – researcher communication during the informed consent process has characterized such interactions as being informative. The present research provides participants' perceptions of the informed consent process, factors that affect their decisions to participate, in addition to highlighting participants' relationships with the various professionals involved. A telephone survey was conducted with 60 participants previously enrolled in one of five drug trails. Findings indicated that the majority of participants perceived the informed consent process was valid, understood their rights as participants, had a high level of trust for the professionals involved, and with self-benefit as one of the first reasons for participating. Conclusions focus on various factors that researchers should be aware of when conducting the informed consent process, particularly in the areas of risks and benefits.

Key Words: Informed Consent, Participants' Perceptions, Clinical Trials, Multidisciplinary, Risks

An Interdisciplinary Approach to the Informed Consent Process: Factors that Affect Participants' Perceptions of the Informed Consent Process

A participant's informed consent (IC) is an essential element of a clinical research trial. The IC is purported to be evidence of participants' understanding of treatments and conditions pertaining to the research. Various multidisciplinary professionals such as research investigators, coordinators, physicians, nurses, and staff play an important role in this process. Necessary elements of the IC process are put forth in Good Clinical Practice Guidelines (United States Department of Health and Human Services, n.d.a). However, there remain difficulties in describing precisely what is known by participants and what factors influence participants. This study explored patients' perceptions of the IC and the various factors that may have influenced patients' decisions to participate in research trails. In addition, this study explored patients' perceptions of their interactions with various professionals involved in the research.

Review of Literature

Protection of human subjects gained prominence due the research conducted by the Tuskegee Institute and the publication of Nazi War crimes. As a result, the Nuremberg Code, Declaration of Helsinki, and Belmont Report were written to protect human subjects and the IC was an important part of those initiatives. Even with the ethical deficiencies that occurred in historical research studies and the initiatives formed from these deficiencies, recent studies have been questioned with regards to the protection of human subjects. Two recent research studies have included participants who have died as a result of their choice to participate in a research study (Grilley & Gee, 2003; Zuker, 2001). These deaths and the associated ethical controversies concerning the IC process have again created attention as to how research studies are being

evaluated and conducted (Aaronson et al., 1996; Bauchner, 2002). At many universities, Institutional Review Boards (IRB) for the Protection of Human Subjects are becoming more restrictive in their evaluation and approval of research studies. A fairly new requirement when seeking approval from IRB committees is that anyone wanting to conduct research with human subjects must participate in two hour training, *Human Participant Protections Education for Research Teams* (National Cancer Institute, 2005). Professional education received through the training details the requirements of the IC process.

Within the United States, every state has legal precedents that define and determine the required disclosure standards for IC. It is the legal and ethical right of a participant regarding the choice he or she will make when agreeing to participate in research (Farrow & O'Brien, 2003). The IC process in research is viewed as the communication between a participant and a researcher resulting in an informed individual. The goal of the IC process is to ensure that a participant has sufficient information to determine whether research participation is most compatible with their individual interests, needs, and values. The IC in research is simple in theory but complex in practice. There have been some studies that have argued that the IC is nothing "... more than a ritual" (Hall, 2001, p. 291; Tatersall, 2001). A recent concern with the IC is the adequate disclosure of all aspects of information in a clinical research study.

Federal regulations require that a complete IC include at least the following elements: (a) nature, purpose, and description of the study; (b) time involved during participation; (c) any alternatives procedures; (d) confidentiality procedures; (e) relevant risks, benefits, and compensations; (f) name of a professional to contact; (g) participant's understanding of the study; and (h) participant's voluntary acceptance (United States Department of Health and Human Services, n.d.b.; Farrow & O'Brien, 2003; Gulam, 2004). In medicine to insure a participant's

agreement is voluntary, the researcher, physician, nurse, coordinator, and staff involved in the research should make it clear to a patient that the "patient" is to make the decision whether to participate. It should be clear a patient is not merely going through a ritual of signing a form.

According to Aaronson et al. (1996) and Wear (1998), an overwhelming majority of patients do want to be informed, while at the same time, some patients skim IC documents; not taking them seriously. Most patients believed consent forms are to protect the physician however: patients are more likely to refuse to participate in a study when they are not informed (Wear, 1998). According to Horng and Grady (2003) researchers, physicians, study coordinators, and IRB committee members, as well as patients, struggle with understanding information presented to patients in research studies. One of the requirements of IC is that participants understand the information related to a research study. This does not mean perfect understanding. Instead, it requires a level of understanding that is adequate to make an informed decision. A contributing factor of concern for patients who agree to participate is that they may be in a desperate state of confusion, anxiety, and vulnerability (Aaronson et al., 1996; Farrow & O'Brien, 2003; Moreno, 2003). Several studies also reported that educational level is associated with participants' abilities to understand and comprehend certain components of the IC such as the scientific methodology (Bauchner, 2002; Cassileth, Zupkis, Sutton-Smith, & March, 1980; Joffee, Cooke, Cleary, Clark, & Weeks, 2001a; Joffee, Cooke, Cleary, Clark, & Weeks, 2001b) and complex words and confusing details (Hochhauser, 2004).

Other factors can affect the status of IC. Therapeutic misconception being one factor, defined by Appelbaum, Roth, Lidz, Benson, and Winslade (1987) as when patients confuse participation in a research study as the same type of care received in their medical care (Fried, 2001; Horng & Grady, 2003; Joffee et al., 2001b; Moss, 2002a). While other factors may include

when participants do not understand what randomization is in a research study; are not aware that they are involved in a research study; or do not understand the possible risks they are taking (Joffee et al., 2001b). Participants may believe that their health care is the main concern of treatment or agree to participate thinking the benefits they will receive are more than described in the research study. In a recent study, Getz and Borfitz (2002) reported that 60% of participants volunteered thinking they would find a cure to their illness or believed that personal benefit would be a component of their decision to participate. Some researchers reported that there are still some patients who participate in research based only on altruistic motives (Jagsi & Lehmann, 2004; e et al., 2001b; Moss, 2002a).

Researchers, physicians, coordinators, nurses, and staff also should be sensitive to the impact of patients' beliefs or misunderstandings during the IC process arising out of the physician-patient relationship. This relationship can create coercive or manipulative forces, intended or not. According to Hall (2001) "any agreement obtained through manipulation or coercion is not informed consent" (p. 291). Though there has been a shift from the paternalistic viewpoint, trust continues to be a powerful factor in the physician-patient relationship. As Macklin (1999) reported from a patient's viewpoint when referring to her physician "Oh, I love that man" (p. 86). In another study, 73% of participants reported that they had concerns because of the possible influence participating in a study may have on their relationship with their doctor (Aaronson et al. 1996). Moss (2002a) cautioned that enrollment in research by patients wanting to please their physician is not good practice. Rather, effective communication by all of the professionals involved in the research in addition to the physician should include honesty, confidentiality, and empathy; not duress, pressure, or secrecy (Gulam, 2004; Switankowsky, 1999).

Nursing and the nursing process also plays an important role in the IC process. Little research has been conducted concerning nurses' contribution to the IC process (Jenkins, n.d.). Significant gains were reported in patient recall of information in addition to obtaining new information after a single contact with a nurse subsequent to the physician having obtained IC. Patients reported nurses assisted them in understanding the IC while providing support to the patient. Other researchers also confirmed the importance of the nurse in assisting patients and making sure patients are not being coerced or pressured to participate (Erlen, 2000; Joffee, 2001a; Joffee, Weeks, Cook, Cleary, & Clark, 2001).

In spite of the concerns discussed, a recent study of participants' understanding of the IC process reported that the majority of participants "... clearly understood the main reasons ..." for research (Spencer et al. 2004, p 41). In one study, 80% of the participants reported they understood the study very well prior to giving their IC (Getz & Borfitz, 2002). Also, satisfaction with the IC was reported by 90% of respondents (Joffee et al., 2001b; Joffee et al., 2001). The majority of "... patients believe that they read the IC carefully and had received adequate explanations" (Moss, 2002a, p. 1). The purpose of the current study is to explore research participants' perceptions regarding the IC process and the various factors that may influence their decisions to participate. In addition, this study explored participants' perceptions of their relationships with the various professionals (i.e. investigator/physician, clinical research coordinator/nurse, and staff) involved in the IC process.

Method

A telephone survey was conducted with 60 clinical research participants to record their perceptions of the IC, factors that influenced their decisions to participate, and perceptions of

their relationship with the professionals involved in the IC procedures. The research setting was in a cardiovascular private practice clinic that was participating in five multi-center double-blind randomized drug trials (i.e. phase 3 & 4). Volunteer participants of these clinical drug trials were asked if they would agree to a follow-up telephone survey concerning the IC process in which they participated during the drug trials. No inducements of any kind were offered. This study was approved by an IRB committee. Participants were contacted by phone approximately four months after their last research encounter and were asked if they were willing to participate in the present study involving the IC process. Participants were reminded that the phone survey was being conducted as a separate event from the original drug trials in which they had taken part.

As the investigator, the physician explained the drug trial to each patient. There was one program administrator who directed all research being conducted in the private practice in addition to other private practice clinics within the physician group. The program administrator had no direct contact with the participants. The clinical research coordinator, the nurse was the site administer for the five drug trials whose duties were delegated by the investigator and program administrator. This nurse conducted a thorough IC with each participant. Three staff employees were also available to answer patients' questions and were available for further information. One staff member was trained to be the phone interviewer regarding the procedures for conducting the phone surveys. The interviewer was instructed to repeat questions that were not understood by a participant up to three times, whereupon she was instructed to move to the next question. The interviewer was not to explain any questions during the surveys to protect validity and consistency of the research.

The phone survey was conducted during the hours of 8:00 a.m. and 9:00 p.m. on Mondays through Fridays over a six month period and took approximately 30 to 45 minutes to complete.

Questions for the survey were based on the required elements of the Code of Federal Regulations as described earlier in this paper (US DHHS, n.d.b). There were also questions based on participants' reasons for participating in the trials and participants' perceptions of their relationships with the professionals involved in the IC process. All questions were written at a six grade reading level. Face validity of the survey was evaluated by three experts: (a) an experienced university and private practice-based research physician, (b) a research program administrator, and (c) a research program coordinator. The survey included a demographic section and a question section.

The survey in its entirety is available from the authors upon request. Shortened versions of each question are provided in Tables 1 and 2. The demographic section included gender, age, and level of education. The question section initially included 42 questions. As suggested by Cohen and Swerdlik (2002), to check for validity and reliability the authors chose four questions with a reverse answer format in addition to a randomized listing of questions regarding elements of the IC. The progress of the survey process and participants' responses were reviewed after the 38th interview. Wording was revised for five questions (4, 26, 27, 28, & 34) due to the high incidence of participants' requests for those questions to be repeated. Results from those five questions were not included in the analysis for this study. Of the remaining 37 questions, the researchers added three questions after the 38th phone survey to identify priorities given for participants' reasons for participation in the drug trials (see Table 2, Section 5).

Twenty-four questions used a 5-point Likert scale ranging from 5 (*Strongest Agree*), 4 (*Agree*), 3 (*Neutral*), 2 (*Disagree*), and 1 (*Strongest Disagreement*). Five questions used a response format of *Yes*, If you Agree or *No*, if you Do Not Agree. Four questions used five percentages (0 %, 25%, 50%, 75%, or 100%). One question used the following choice format of

Physician or Nurse. Three questions used a six choice rank order format: (a) *Benefit to Yourself*, (b) *Benefit to Future Patients*, (c) Benefit to Society, (d) *Made Physician Happy*, (e) *Made Nurse Happy*, or (f) *Free Care*.

A frequency distribution was used to examine the frequency and percentage of participants' responses. Using the basic elements for the IC process required by the Code of Federal Regulations (US DHHS, n.d.b) as a model, the frequency results are divided into the following four sections: Section 1, *Participants' Perceptions of IC Information*, Section 2, *Rights of Participants and Risks and Benefit*, Section 3, *Participants' Perceptions of Professionals*, and Section 4, *Participants' Reasons for Participating*.

Sample Description

The sample for this study consisted of 69 research participants who volunteered to take part in one of five drug trials (Trial I, n = 10; Trial II, n = 14; Trial III, n = 1; Trial IV, n = 14; Trial V, n = 18; missing, n = 3). Of the 69 subjects, 9 declined to participate in the follow-up phone survey. Participants included 39 men, 17 women, with 4 not reporting their gender. There were 50 Caucasians, 3 African Americans and 7 did not report their race. Ages ranged from 46 to 103 (M = 70.8). The level of education for participants included 25 with no formal education, 3 grade school, 15 high school, 7 college, and 10 did not report their educational level.

Participants' Perceptions of IC Information – Section 1

There were ten questions concerning participants' perceptions of the IC information (see Table 1, Section 1). When participants were asked if they were given the name of the illness they were being treated for, 95% (Q29) strongly agreed. Over 93% (Q31) believed that all the requirements of the IC process were explained in addition to the confidentiality procedures

(Q32). Over 88% (Q33) said they were told the time requirements. When asked whether participants understood the terms, 70% (Q20) strongly agreed they understood. When asked if there was information that was confusing, responses varied from 36.7% (Q25) strongly agreed, 20% were neutral, and 36.7% strongly disagreed. When asked what percentage of the IC was explained by the physician, 30% (Q36) reported all of the information; 16.7% reported three-fourth; 23.3% reported one-half, 6.7% reported one-fourth, and 3.3% reported none. When asked what percentage of the information explained by the physician did they understand, 65% (Q37) reported all of the information, 5% reported three-fourth, 5% reported one-half, and 1.7% reported one-fourth. When asked what percentage of the IC was explained by the nurse, 40% (Q35) reported all of the information, 35% reported three-fourth, 8.3% reported one-half, and 1.7% reported one-fourth. When asked what percentage of the information explained by the nurse did they understand, 68.3% (Q38) reported all of the information, 15% reported three-fourth, 1.7% reported one-half, and 1.7% reported one-fourth.

Rights of Participants – Section 2

There were ten questions concerning rights of participants (see Table 1, Section 2). For two questions (Q1 & 9), over 98% participants strongly agreed they were informed that they could make their own decision regarding participation and that they were informed that they could stop at any time. Over 68% (Q10) strongly agreed that they were informed of who to call if they had questions. Over 16% (Q14) strongly agreed they were not rushed while 80% reported they were rushed. Over 83% (Q16) strongly agreed they were allowed time to discuss the study with others. Over 91% (Q17) strongly agreed they were treated as an adult. Regarding expenses, responses varied with over 56% (Q18) who strongly agreed they were informed how expenses would be handled, 18.3% were neutral, while 21.7% strongly disagreed that they were informed of how

expenses would be handled. Information regarding their rights as a person, 90% (Q22) strongly agreed they were informed and 80% (Q23) strongly agreed their rights were respected. Finally, 83.3% (Q24) strongly agreed they were informed that they could consult others.

Risks and Benefits - Section 2

There were five questions concerning participants' risks and benefits (see Table 1, Section 2). Over 91% (Q2) strongly agreed they were informed that they may be helped as a result of taking part in the research study. Over 81% (Q3) strongly agreed they were informed of the risks. Only 50% (Q5) strongly agreed they were informed that it was possible they may suffer from taking part in the research study, 3.3% agreed, 11.7% were neutral while, 35.7% strongly disagreed they were informed that they may suffer. Over 73% (Q7) strongly agreed that the benefits related to taking part in the study were listed. Ninety percent (Q12) strongly agreed they were informed that they may help others as a result of participating in the research study.

Participants' Perceptions of Professionals – Section 3

There were nine questions related to participants' relationships with professionals (i.e. investigators/physician, coordinator/nurse, or staff (see Table 2, Section 3). Two questions (30 & 39) were related to participants' perceptions of the physician and nurse. For the first question (Q30), 95% understood that their relationship with their physician would not change if they chose to stop participation. For the second question (Q39), 50% of the participants responded that the physician influenced their decision to participate while 40% stated the nurse did.

Regarding participants' relationships with the physician, 98.3% (Q8) strongly agreed they trusted the physician and 95% (Q13) strongly agreed their physician was trustworthy. Also, 90% (Q15) strongly agreed their physician wanted them to participate. Regarding participants' relationship with the nurse, 96.7% (Q6) strongly agreed they trusted the nurse and 60% (Q11) strongly agreed

the nurse wanted them to participate. When questioned whether the nurse pressured them into participating, 30% (Q19) strongly agreed, 16.7% were neutral, and 50% strongly disagreed. Over 88% (Q21) strongly agreed they trusted the other staff.

Reasons for Participating – Section 4

As stated earlier, three questions (40, 41, & 42) were added after the 38th survey was given related to reasons participants gave for participating in the studies (see Table 2, Section 4). Twenty-two participants rank ordered the reasons they were taking part in the clinical study. The following were ranked first by participants (Q40); Benefit to Self (63.6%), Benefit to Future Patients (13.6%), Benefit to Society (13.6%), and Free Care (9.1%). The following were ranked second by participants (Q41); Benefit to Self (18.2%), Benefit to Future Patients (36.4%), Benefit to Society (13.6%), Make Physician Happy (4.5%), and Free Care (27.3%). The following were ranked third by participants (Q42); Benefit to Future Patients (13.6%), Make Physician Happy (22.7%), Make Nurse Happy (45.5%), and Free Care (18.2%).

Discussion

This survey study was conducted to explore research participants' perceptions surrounding the IC process and various factors that influence their decisions to participate. Previous research has stressed that participants are not attentive to the IC process and view it as a nothing more than a ritual. In general, it seemed that participants believed in this study that the IC process was valid. They believed that the required elements and concepts were presented. Participants reported being satisfied with the IC process and found that their rights as participants were upheld. Few reported feeling coerced and most felt they were allowed to discuss the research study with others. Participants recalled they were informed that they may be helped and the

relevant risks. Although, the majority of participants indicated that they understood their right to make an autonomous and thorough decision several felt a high degree of time pressure or being rushed to make the decision.

In agreement with Macklin's (1999) study, participants indicated a high level of trust for the physician. They also trusted the staff and the nurse but a higher number felt more direct influence from the nurse. Pleasing the physician or nurse ranked fairly low, appearing only as third choice. Many participants identified self benefit as one of the first or second reasons for participating. More chose society and future patients' benefits, as the first, second or third reason for participation, indicating a high level of altruism.

If we use any response with less than 70% agreement in the predominant answers as an indicator of variability in the answers, there were several areas where participants' responses varied enough to call attention to that area. As suggested by Hochhauser (2004) participants find terminology in research studies confusing as did participants in this study. Also, participants' understanding of the IC depended on whether the doctor or nurse explained the IC. There was variability among participants with respect to being informed about whom to call with questions or how expenses would be handled. Again as noted by previous studies (Jagsi & Lehmann, 2004; Joffee et al., 2001b) participants may not recognize the risks involved in a research study or whether participants would benefit from participating. In this study, there was variability in participants' perceptions with respect to their awareness that they may suffer and the level of certainty that participating in the study would benefit participants.

There were three specific limitations to this study. First, although all five drug trials were held within the same private practice, each trial involved a different type of drug study. Second, participants who refused to participate in the trials initially were excluded in this sampling frame.

Finally, this study involved participants' responses to a phone survey which may have been influenced by their need to respond as expected by family members or professionals.

Conclusions

The communication of adequate information and assurance of voluntary decision making are general ethical principles that researchers and all health care professionals involved in research must uphold in IC procedures. Generally, participants do believe that they are being informed about research conditions. Most participants however continue to view clinical research as a personal benefit in their health care and chose to participate because of their perceived benefits. Trust in the physician and the nurse is also an important factor when patient chose to participate. Participants in this study as did previous studies were concerned with the complexity of the scientific terminology used in health care and research. Our results suggest a call for awareness by all professionals of the many factors that influence vulnerable potential participants and the seriousness of professionals' responsibility when conducting research and the IC process, particularly in the areas of risks and benefits as suggested by Joffee et al. (2001b). The personal bond between health care professionals and patients has long been considered an essential element of the medical environment and may challenge parts of the underlying objective of IC, which is to balance the natural disparity in power due to knowledge between participants and the professionals involved. The transmission of information from the coordinator, physician, nurse, or staff to patients is a part of the larger IC issue. If the information disclosed during research replaces rather than supplements the balanced health care provider-patient relationships, some very important underpinnings of participant IC may be sacrificed.

Table 1 – Percentages of Participants' Responses- Sections Required by the Code of Federal Regulations (n = 60)

Section 1

	Yes		n		N		n		M		n	
Consent Information Given the name of illness - Q29	05.0								5.0		2	
~	95.0		5 .6		1.7		1		5.0		3	
Explained everything required - Q31	93.3		56		1.7		1		5.0		3	
Confidentiality of records - Q32	93.3		56		1.7		1		5.0		3	
Explained time required - Q33	88.3		53		5.0		3		6.7		4	
	SA	n	A	n	N	n	D	n	SD	n	M	n
Participants Understanding												
Understood terms - Q20 (rvd)	70.0	42			16.7	10	1.7	1	8.3	5	3.3	2
*Information confusing - Q25	36.7	22	1.7	1	20.0	12			36.7	22	5.0	3
	100%	n	75%	n	50%	n	25%	n	0%	n	M	n
By Physician												
*IC explained - Q36	30.0	18	16.7	1	0 23.3	14	6.7	4	3.3	2	20.0	12
*Understood what explained by	20.0		1017	-	0 20.0		0.,		0.0	_	_0.0	
Physician - Q37	65.0	39	5.0	9	5.0	3	1.7	1			13.3	8
Thysician Q57	05.0	37	3.0		5.0	3	1.,	•			13.3	O
By Nurse												
*IC explained - Q35	40.0	24	35.0	2	1 8.3	5	1.7	1			15.0	9
*Understood what explained by	-10.0	27	33.0		1 0.5	3	1./	1			13.0	
	68.3	41	15.0	9	1.7	1	1.7	1			12.2	8
Nurse - Q38	08.3	41	13.0	9	1.7	1	1./	1			13.3	0
Section 2												
Section 2	ÇΛ		Δ	10	N		D	10	SD.	10	M	
	SA	n	A	n	N	n	D	n	SD	n	M	n
Rights of Participants			A	n			D	n	SD	n	M	n
Rights of Participants Make own decision – Q1	98.3	59	A	n	1.7	1	D	n	SD	n	M	n
Rights of Participants Make own decision – Q1 Can stop at any time - Q9	98.3 98.3	59 59			1.7 1.7	1 1	D				M	n
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd)	98.3 98.3 68.3	59 59 41	A 5.0	<i>n</i>	1.7	1	D		23.3	14		
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14	98.3 98.3 68.3 16.7	59 59 41 10	5.0	3	1.7 1.7 3.3	1 1 2	D		23.3 80.0	14 48	3.3	2
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16	98.3 98.3 68.3 16.7 83.3	59 59 41 10 50			1.7 1.7 3.3 1.7	1 1 2	D		23.3	14	3.3 3.3	2 2
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17	98.3 98.3 68.3 16.7 83.3 91.7	59 59 41 10 50 55	5.0	3	1.7 1.7 3.3 1.7 5.0	1 1 2 1 3	D		23.3 80.0 10.0	14 48 6	3.3 3.3 3.3	2 2 2
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18	98.3 98.3 68.3 16.7 83.3 91.7 56.7	59 59 41 10 50 55 34	5.0	3	1.7 1.7 3.3 1.7 5.0 18.3	1 1 2 1 3 11	D		23.3 80.0 10.0 21.7	14 48 6	3.3 3.3 3.3 3.3	2 2 2 2
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0	59 59 41 10 50 55 34 54	5.0	3	1.7 1.7 3.3 1.7 5.0 18.3 3.3	1 1 2 1 3 11 2	D		23.3 80.0 10.0	14 48 6	3.3 3.3 3.3 3.3 5.0	2 2 2 2 2 3
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22 Rights were respected - Q23	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0 80.0	59 59 41 10 50 55 34 54	5.0 1.7	3	1.7 1.7 3.3 1.7 5.0 18.3 3.3 8.3	1 1 2 1 3 11	D		23.3 80.0 10.0 21.7	14 48 6	3.3 3.3 3.3 5.0 11.7	2 2 2 2
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0	59 59 41 10 50 55 34 54	5.0	3	1.7 1.7 3.3 1.7 5.0 18.3 3.3	1 1 2 1 3 11 2 5	D		23.3 80.0 10.0 21.7	14 48 6	3.3 3.3 3.3 3.3 5.0	2 2 2 2 2 3 7
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22 Rights were respected - Q23 Informed could talk to anyone - Q24 Risks and Benefits	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0 80.0 83.3	59 59 41 10 50 55 34 54 48 50	5.0 1.7	3	1.7 1.7 3.3 1.7 5.0 18.3 3.3 8.3 5.0	1 1 2 1 3 11 2 5 3	D		23.3 80.0 10.0 21.7 1.7	14 48 6 13 1	3.3 3.3 3.3 5.0 11.7	2 2 2 2 2 3 7
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22 Rights were respected - Q23 Informed could talk to anyone - Q24 Risks and Benefits Informed may be helped - Q2	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0 80.0 83.3	59 59 41 10 50 55 34 48 50	5.0 1.7	3	1.7 1.7 3.3 1.7 5.0 18.3 3.3 8.3 5.0	1 1 2 1 3 11 2 5 3	D		23.3 80.0 10.0 21.7 1.7 5.0	14 48 6 13 1 3	3.3 3.3 3.3 5.0 11.7 5.0	2 2 2 2 3 7 3
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22 Rights were respected - Q23 Informed could talk to anyone - Q24 Risks and Benefits Informed may be helped - Q2 Relevant risks explained - Q3 (rvd)	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0 80.0 83.3	59 59 41 10 50 55 34 54 48 50	5.0 1.7 1.7	3 1	1.7 1.7 3.3 1.7 5.0 18.3 3.3 8.3 5.0	1 1 2 1 3 11 2 5 3	D		23.3 80.0 10.0 21.7 1.7 5.0	14 48 6 13 1 3	3.3 3.3 3.3 5.0 11.7	2 2 2 2 2 3 7
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22 Rights were respected - Q23 Informed could talk to anyone - Q24 Risks and Benefits Informed may be helped - Q2 Relevant risks explained - Q3 (rvd) *Informed possible will suffer - Q5	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0 80.0 83.3	59 59 41 10 50 55 34 54 48 50	5.0 1.7 1.7 1.7 3.3	3 1 1 2	1.7 1.7 3.3 1.7 5.0 18.3 3.3 8.3 5.0	1 1 2 1 3 11 2 5 3 3 5 7	D		23.3 80.0 10.0 21.7 1.7 5.0 5.0 6.7 35.0	14 48 6 13 1 3	3.3 3.3 3.3 5.0 11.7 5.0	2 2 2 2 3 7 3
Rights of Participants Make own decision – Q1 Can stop at any time - Q9 *Informed whom to call – Q10 (rvd) Weren't rushed - Q14 Allowed to discuss with others - Q16 Treated as an adult - Q17 *Informed how expenses handled Q18 Informed rights as a person - Q22 Rights were respected - Q23 Informed could talk to anyone - Q24 Risks and Benefits Informed may be helped - Q2 Relevant risks explained - Q3 (rvd)	98.3 98.3 68.3 16.7 83.3 91.7 56.7 90.0 80.0 83.3	59 59 41 10 50 55 34 54 48 50	5.0 1.7 1.7	3 1	1.7 1.7 3.3 1.7 5.0 18.3 3.3 8.3 5.0	1 1 2 1 3 11 2 5 3	D		23.3 80.0 10.0 21.7 1.7 5.0	14 48 6 13 1 3	3.3 3.3 3.3 5.0 11.7 5.0	2 2 2 2 3 7 3

Note: SA = Strongest Agree, A = Agree, N = Neutral, D = Disagree, SD = Strongest Disagree, M = Missing, and n = number of participants.

Note: * Indicates questions with less than 70% agreement in predominant answers for a particular question. Note" (rvd) = reversed score

<u>Table 2 - Percentages of Participants' Responses to Professional Section (n = 60)</u>

Section 3

Participants' Perceptions of Professionals

			Ye	S		n	No		n	M		n
Relationship with Physician will not change – Q30						57				5.0		3
			Ph	ysici	an	n	Nurse	;	n	M		n
Professional influenced your participation – Q39						30	40	2	24	10.0		6
	SA	n	A	n	N	n	D	n	SD	n	M	n
Doctor												
Trust Physician - Q8	98.3	59							1.7	1		
Trustworthy Physician - Q13 (rvd)	95.0	57							1.7	1	3.3	2
Physician wanted participate - Q15	90.0	54			6.7	4					3.3	2
Nurse												
Trust Nurse - Q6	96.7	58									3.3	2
Nurse wanted participate - Q11	60.0	36			18.3	11			21.7	13		
Pressured by Nurse - Q19	30.0	18			16.7	16			50.0	30	3.3	2
Employees												
Trust Staff - Q21	83.3	53	3.3	2	5.0	3					3.3	2

Percentages of Participants' Responses to Reasons for Participating (n = 22)

Section 4

	Benefit Self		Benefit Future		Benefit Society		Doctor Happy		Nurse Happy		Free Care	
		n	Patients	n		n		n		n		n
Reasons for Participating 1st Ranked – Q40 2nd Ranked – Q41 3rd Ranked – Q42	63.6 18.2	14 4	13.6 36.4 13.6	3 8 3	13.6 13.6	3 3	4.5 22.7	1 5	45.5	10	9.1 27.3 18.2	2 6 4

Note: SA = Strongest Agree, A = Agree, N = Neutral, D = Disagree, SD = Strongest Disagree, M = Missing, and n = number of participants.

Note: * Indicates questions with less than 70% agreement in predominant answers for a particular question.

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