Enhancing awareness of research participants' bill of rights: a study in a rural municipality in the Philippines

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Abstract

Introduction Documenting a research participant's awareness of the bill of rights is achieved with an informed consent. In recent years, the informed consent document has increasingly become confounding to research participants in its complexity. As such, the awareness of research participants' bill of rights has emerged as a lingering issue since studies that test awareness of research participants' bill of rights are limited. Hence, this study aimed to determine the participants' awareness of the bill of rights after an educational intervention.

Methods A quasi-experimental study was done where participants' awareness of clinical trial participants' bill of rights was determined after an educational intervention.

Results There was a significant difference ($p < 0.001$) in awareness of the elements of the bill of rights (including voluntary participation, being told about the benefits and risks of participating in the study and right to withdraw from the study) after the intervention except for the element which asked about the details describing clinical trial objectives and activities. A significant difference was observed before and after intervention among females, middle aged participants and older, among those who did not complete high school and among those unemployed. Their awareness of the elements of the bill of rights was lesser than their counterparts.

Conclusions Significant difference in the awareness of bill of rights was observed after the educational intervention. Additional intervention could be given to participants who are females, of older age group (middle age and older), did not complete high school, and the unemployed when they participate in clinical trials to ensure their awareness of the bill of rights of clinical trial participants. Varied learning materials must be given to participants to emphasize the clinical research objectives and activities as well.

Key words: Bill of rights, research participants, clinical trials, informed consent

Documenting a study participant's awareness of the bill of rights as applied to clinical research is commonly believed to be achieved with an informed consent. It is a widely accepted fact that the ethical principles of research which serve as the foundational basis of the research participants' bill of rights are clearly outlined in the informed consent form.

It is therefore not unexpected that a study involving adults with psychiatric conditions, cognitive impairment, and other factors that may affect informed consent reported a substantial increase in published literature on informed consent over the preceding three decades.[1] In a separate study involving researchers working with human participants, findings indicated that most participants understood key components

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of informed consent, including study confidentiality, the nature of the study, compensation, voluntariness, and the right to withdraw.[2] These elements are also articulated in established guidance documents, such as the *Bill of Rights of Research Participants* issued by the University of Iowa Human Subjects Office / Institutional Review Board.[3]

Indeed, a meta-analysis study found that participants demonstrated the highest level of understanding (over 50%) regarding voluntary participation, blinding (excluding knowledge about investigators' blinding), and freedom to withdraw at any time, and that only a small minority of patients demonstrated comprehension of placebo concepts, randomisation, safety issues, risks, and side effects.[4]

While the informed consent document is increasingly confounding to research participants in its complexity, the essential elements that uphold the research participants' bill of rights must always be upheld by researchers while study or research participants' awareness must be assured. However, studies that actually test awareness of research participants' bill of rights is limited.

In this study, the authors utilized the *Research Participants' Bill of Rights* developed by the Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard University. This document, designed to promote ethical standards and participant protection in clinical research, outlines essential rights that should be communicated to individuals involved in research.[5] The authors included only the elements relevant to the diagnostic trial ongoing at the time of the study. These elements were: (1) right to be treated in a polite and caring manner. (2) right to be told what the study is trying to find out and why it might - or might not- be a good option for you. (3) right to understand every form you are asked to sign or fill out. (4) right to be told about possible side effects or discomforts that might happen during the study, (5) right to be told about any benefits from being in the study, (6) right to ask any questions about the study, (7) right to take your time when you're deciding if you want to be in the study, (8) right to refuse to be in the study, or to change your mind about being in the study after it has started, and (9) right to receive a copy of the consent form you sign if you decide to join the study. Some elements of the original document were excluded from the analysis as they were not relevant to the objectives of the current study.

In this study, the authors focused on determining whether awareness of research study participants' bill of rights could be improved with educational intervention. To our knowledge, this is among the first of studies on awareness of research participants' bill of rights in clinical trials a rural context in the Philippines.

Methods

This was a quasi-experimental study which included all study participants of an ongoing clinical study who were of legal age with no cognitive impairment and consented to participate in the study.

Ethics approval was obtained from the University of the East Ramon Magsaysay Memorial Medical Center Research Institute for the Health Sciences Ethics Research Committee.

This flowchart illustrates the sequence of activities undertaken by study participants, from enrollment to post-intervention assessment and feedback (Figure 1).

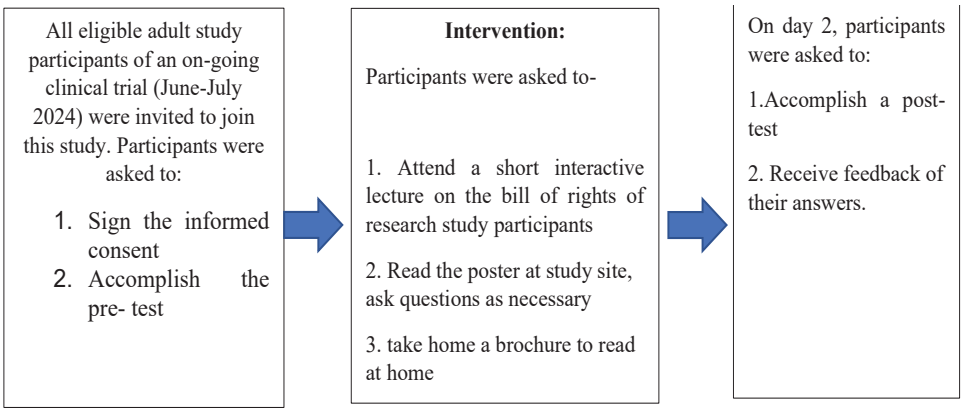

Figure 1. Schema of the study.

The informed consent form, educational materials (contents of poster/ tarpaulin and brochure) were translated from English to the native language of the region (Waray) by 2 native speakers who have been living in the study site for at least 10 years. The pre and post-test was adapted from Bill of rights for research participants and translated also to Waray by the 2 native speakers previously described.

The difference in number of participants who answered yes in the pre and post-test was determined by Chi square test and Fisher's test at $p<0.05$

Results

There were a total of 263 participants. Table 1 shows the age distribution of the participants with 125 (48%) females and 138 (52%) males. After the educational intervention, there was a significant difference in the awareness of the elements of the bill of rights, except for element which describes the clinical trial's objectives and activities. There was also a significant difference between the 2 groups, with significantly less females answering yes indicating lesser awareness of the elements of the bill of rights.

Table 2 presents the age distribution based on WHO classification: 43 participants (16%) were categorized as youth (18–24 years), 113 (43%) as young adults (25–44 years), 73 (28%) as middle-aged (45–60 years), 33 (12.5%) as elderly (61–75 years), and 1 participant (0.4%) as senile (76–90 years).

Following the intervention, a significant improvement in awareness of the elements of the Research Participants' Bill of Rights was observed, with the exception of Element 2, which pertains to understanding the objectives and activities of the clinical trial. A statistically significant difference in awareness was also noted across age groups, with older participants (middle-aged, elderly, and senile) demonstrating lower awareness, as reflected by fewer affirmative ("yes") responses.

Table 3 presents the educational attainment of the participants. Two participants (0.8%) did not complete primary school, 63 (24%) completed only elementary or primary education, and 198 (75%) were high school graduates.

Following the educational intervention, there was a significant increase in participants' awareness of the elements of the Research Participants' Bill of Rights, with the exception of the element describing the clinical trial's objectives and activities. A significant difference in awareness was also observed across educational attainment groups, with high school graduates demonstrating greater awareness compared to those with lower levels of education.

Table 1. Comparison of distribution of participants before and after intervention according to sex (Total n= 263).

BOR	No to Yes		Yes to Yes		No to No		No to unrecalled		Yes to unrecalled	
Element	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)	Female N=125, n (%)	Male N=138, n (%)
1- right to be treated in a polite and caring manner.	56 (44.8%)	58 (42%)	26 (20.8%)	69 (50%)	N/A	N/A	43 (34.4%)	10 (7.2%)	0 (0%)	1 (0.7%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	71 (56.8%)	93 (67.4%)	9 (7.2%)	9 (6.5%)	N/A	N/A	45 (36%)	36 (26.1%)	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	61 (48.8%)	50 (36.2%)	30 (24%)	74 (53.6%)	N/A	N/A	33 (26.4%)	13 (9.4%)	1 (0.8%)	1 (0.7%)
4- right to be told about possible side effects or discomfort that might happen during the study.	49 (39.2%)	118 (85.5%)	0 (0%)	2 (1.4%)	1 (0.8%)	0 (0%)	75 (60%)	18 (13%)	N/A	N/A
5- right to be told about any benefits from being in the study.	59 (47.2%)	124 (89.9%)	N/A	N/A	1 (0.8%)	0 (0%)	65 (52%)	14 (10.1%)	N/A	N/A
6-right to ask any questions about the study.	67 (53.6%)	126 (91.3%)	N/A	N/A	1 (0.8%)	0 (0%)	57 (45.6%)	12 (8.7%)	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	91 (72.8%)	97 (70.3%)	10 (8%)	35 (25.4%)	1 (0.8%)	0 (0%)	23 (18.4%)	6 (4.3%)	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	65 (52%)	125 (90.6%)	N/A	N/A	1 (0.8%)	0 (0%)	59 (47.2%)	13 (9.4%)	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	18 (14.4%)	53 (38.4%)	N/A	N/A	40 (32%)	14 (10.1%)	67 (53.6%)	71 (51.4%)	N/A	N/A

Table 2. Comparison of distribution of participants before and after intervention according to age classification (N= 263).

BOR	No to Yes					Yes to Yes				
Element	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)
1- right to be treated in a polite and caring manner.	22 (51.2%)	57 (50.4%)	27 (37%)	29 (46%)	0 (0%)	17 (39.5%)	50 (44.2%)	22 (30.1%)	7 (11.1%)	0 (0%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	28 (65.1%)	70 (61.9%)	48 (65.8%)	18 (54.5%)	0 (0%)	2 (4.7%)	6 (5.3%)	6 (8.2%)	4 (12.1%)	0 (0%)
3- right to understand every form you are asked to sign or fill out.	22 (51%)	41 (36.3%)	34 (46.6%)	13 (39.4%)	1 (100%)	13 (30%)	67 (59.3%)	18 (24.7%)	6 (18.2%)	0 (0%)
4- right to be told about possible side effects or discomfort that might happen during the study.	49 (39.2%)	101 (89.4%)	31 (42.5%)	5 (15.2%)	0 (0%)	0 (0%)	1 (0.9%)	1 (1.4%)	0 (0%)	0 (0%)
5- right to be told about any benefits from being in the study.	31 (72.1%)	104 (92%)	38 (52.1%)	10 (30.3%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
6-right to ask any questions about the study.	30 (69.8%)	103 (91.2%)	43 (58.9%)	17 (51.5%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	31 (72.1%)	80 (70.8%)	47 (64.4%)	29 (87.9%)	1 (100%)	6 (14%)	28 (24.8%)	9 (12.3%)	2 (6.1%)	0 (0%)
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	31 (72.1%)	106 (93.8%)	41 (56.2%)	12 (36.4%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	27 (62.8%)	64 (56.6%)	39 (53.4%)	8 (24.2%)	1 (100%)	10 (23.3%)	43 (38.1%)	14 (19.2%)	4 (12.1%)	0 (0%)

BOR	No to No					No to unrecalled					Yes to unrecalled				
Element	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)	Youth N=43, n (%)	Young Adult N=113, n (%)	Middle Age N=73, n (%)	Elderly N=33, n (%)	Senile Age N=1, n (%)
1- right to be treated in a polite and caring manner.	N/A	N/A	N/A	N/A	N/A	4 (9.3%)	6 (5.3%)	23 (31.5%)	19 (57.6%)	1 (100%)	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	N/A	N/A	N/A	N/A	N/A	13 (30.2%)	37 32.7%)	19 (26%)	11 (33.3%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	N/A	N/A	N/A	N/A	N/A	8 (22%)	5 (4.4%)	21 (28.8%)	12 (36.4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (6.1%)	0 (0%)
4- right to be told about possible side effects or discomfort that might happen during the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	13 (30.2%)	11 (9.7%)	40 (54.8%)	28 (84.8%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
5- right to be told about any benefits from being in the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	12 (27.9%)	9 (8%)	34 (46.6%)	23 (69.7%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
6-right to ask any questions about the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	13 (30.2%)	10 8.8%)	29 (39.7%)	16 (48.5%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	6 (14%)	5 (4.4%)	16 (21.9%)	2 (6.1%)	0 (0%)	N/A	N/A	N/A	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	0 (0%)	0 (0%)	1 (1.4%)	0 (0%)	0 (0%)	12 (27.9%)	7 (6.2%)	31 (42.5%)	21 (63.6%)	1 (100%)	N/A	N/A	N/A	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	6 (14%)	6 (5.3%)	20 (27.4%)	21 (63.6%)	0 (0%)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 3. Comparison of distribution of participants before and after intervention according to their educational attainment (N= 263).

BOR	No to Yes			Yes to Yes			No to No		
Element	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)
1- right to be treated in a polite and caring manner.	0 (0%)	29 (46%)	85 (42.9%)	0 (0%)	7 (11.1%)	88 (44.4%)	N/A	N/A	N/A
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	1 (50%)	39 61.9%)	124 (62.6%)	1 (50%)	6 (9.5%)	11 (5.6%)	N/A	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	1 (50%)	34 (54%)	76 (38.4%)	0 (0%)	4 (6.3%)	100 (50.5%)	N/A	N/A	N/A
4- right to be told about possible side effects or discomfort that might happen during the study.	0 (0%)	6 (9.5%)	161 (81.3%)	0 (0%)	0 (0%)	2 (1.4%)	0 (0%)	0 (0%)	1 (0.8%)
5- right to be told about any benefits from being in the study.	0 (0%)	13 20.6%)	170 (85.8%)	N/A	N/A	N/A	0 (0%)	0 (0%)	1 (0.8%)
6-right to ask any questions about the study.	1 (50%)	23 (36.5%)	169 (85.3%)	N/A	N/A	N/A	0 (0%)	0 (0%)	1 (0.8%)
7- right to take your time when you're deciding if you want to be in the study.	2 (100%)	42 (66.7%)	144 (72.7%)	0 (0%)	1 (1.6%)	44 (22.2%)	0 (0%)	0 (0%)	0 (0%)
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	0 (0%)	17 (26.9%)	173 87.3%)	N/A	N/A	N/A	0 (0%)	0 (0%)	1 (0.8%)
9-right to receive a copy of the consent form you sign if you decide to join the study.	0 (0%)	31 (49.2%)	107 (54%)	0 (0%)	4 (6.3%)	67 (33.8%)	2 (100%)	28 (44.4%)	24 (12.1%)

BOR	No to unrecalled			Yes to unrecalled		
Element	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)	No schooling N= 2, n (%)	Elementary only N= 63, n (%)	High School N= 198, n (%)
1- right to be treated in a polite and caring manner.	2 (100%)	27 (42.9%)	24 (12.1%)	0 (0%)	0 (0%)	1 (0.5%)
2- right to be told what the study is trying to find out and why it migaht - or might not- be a good option for you.	0 (0%)	18 (28.6%)	63 (31.8%)	N/A	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	1 (50%)	24 (38.1%)	21 (10.6%)	0 (0%)	1 (1.6%)	1 (0.5%)
4- right to be told about possible side effects or discomfort that might happen during the study.	2 (100%)	57 (90.5%)	34 (0.8%)	N/A	N/A	N/A
5- right to be told about any benefits from being in the study.	2 (100%)	50 (79.3%)	27 (13.6%)	N/A	N/A	N/A
6-right to ask any questions about the study.	1 (50%)	40 (63.4%)	28 (14%)	N/A	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	0 (0%)	20 (31.7%)	9 (4.5%)	N/A	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	2 (100%)	46 (73%)	24 (12.1%)	N/A	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	N/A	N/A	N/A	N/A	N/A	N/A

Table 4 presents the employment status distribution of the participants. Of the total, 91 (35%) were unemployed and 172 (65%) were employed. As with the other variables, a significant improvement in awareness of the elements of the Research Participants' Bill of Rights was observed after the intervention. A significant difference in awareness was also noted between the two groups, with unemployed participants showing lower levels of awareness, as indicated by fewer affirmative responses. This difference was observed across all elements except for Element 2, which pertains to the clinical trial's objectives and activities.

Discussion

The four basic ethical principles in research include respect for autonomy, non-maleficence and beneficence and justice. Documentation of these basic tenets in the ethical conduct of research is achieved through an informed consent process. A previous study explored that consenting to participate in a clinical research study after being properly and correctly informed upholds the basic ethical principle of "autonomy" in human research. The authors outlined the key elements of a robust informed consent process, and that one of which is communication by which the physician sensitizes the participants about the nature, procedures, risks benefits, and treatment schedules of the study in a language that is non-technical and understandable by them.[6]

There are at least two emerging issues that add complexity to the informed consent process in clinical trials. The first is the requirement to disclose all details of the clinical trial to prospective participants. A survey done among clinical trial participants in several Southeast Asian countries pointed out that the use of

Table 4. Comparison of distribution of participants before and after intervention according to employment status (N= 263).

BOR	No to Yes		Yes to Yes		No to No		No to unrecalled		Yes to unrecalled	
Element	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)	Not Employed N=91, n (%)	Employed N= 172, n (%)
1- right to be treated in a polite and caring manner.	38 41.8%)	76 (44.2%)	6 (6.6%)	89 (51.7%)	N/A	N/A	47 (51.6%)	6 (3.5%)	0 (0%)	1 (0.6%)
2- right to be told what the study is trying to find out and why it might - or might not- be a good option for you.	56 (61.5%)	108 (62.8%)	10 (11%)	8 (4.7%)	N/A	N/A	25 (27.5%)	56 (32.6%)	N/A	N/A
3- right to understand every form you are asked to sign or fill out.	50 (54.9%)	61 (35.5%)	1 (1.1%)	103 (59.9%)	N/A	N/A	38 (41.8%)	8 (4.7%)	2 (2.2%)	0 (0%)
4- right to be told about possible side effects or discomfort that might happen during the study.	10 (11%)	157 (91.3%)	0 (0%)	2 (1.2%)	1 (1.1%)	0 (0%)	80 (87.9%)	13 (7.6%)	N/A	N/A
5- right to be told about any benefits from being in the study.	19 (20.9%)	164 (95.3%)	N/A	N/A	1 (1.1%)	0 (0%)	71 (78%)	8 (4.7%)	N/A	N/A
6-right to ask any questions about the study.	27 (29.7%)	166 (96.5%)	N/A	N/A	1 (1.1%)	0 (0%)	63 (69.2%)	6 (3.5%)	N/A	N/A
7- right to take your time when you're deciding if you want to be in the study.	65 (71.4%)	97 (70.3%)	0 (0%)	45 (26.2%)	1 (1.1%)	0 (0%)	25 (27.5%)	6 (3.5%)	N/A	N/A
8- right to refuse to be in the study, or to change your mind about being in the study after it has started.	24 (26.4%)	190 (72.2%)	N/A	N/A	1 (0.8%)	0 (0%)	66 (72.5%)	6 (3.5%)	N/A	N/A
9-right to receive a copy of the consent form you sign if you decide to join the study.	2 (2.2%)	69 (40.1%)	N/A	N/A	47 (51.6%)	7 (4.1%)	67 (46.2%)	96 (55.8%)	N/A	N/A

lengthy, detailed, and complex informed consent forms (ICFs) may not truly promote the rights and interests of research participants. The extent of information in ICFs has been the subject of debates for decades; however, no clear guidance is given.[7]

Furthermore, a study observed that advancements in medical research have led to increasingly complex protocols, resulting in the need to convey elaborate and often intricate information during the informed consent process.[8] The complexity of consent documents is further compounded by the perception of both sponsors and investigators, who often regard the informed consent form primarily as a legal and symbolic document representing the participant's agreement to join the study. As a result, the consent process may fulfill legal requirements but frequently falls short in terms of clarity and comprehensibility for participants.

A survey involving both researchers and research participants highlighted that the informed consent process for clinical research enrollment can be complex for both parties.[9] Challenges include balancing respect for participants' autonomy and information needs with the obligation to provide sufficient details to support an informed decision. Research staff expressed concern about participants' level of understanding—concerns that appear to be supported by studies assessing patient comprehension of research information. The survey emphasized the importance of allocating adequate time for informed consent discussions.

A study conducted at a major research center emphasized that although Institutional Review Boards (IRBs) are responsible for reviewing and approving the content of informed consent materials, the actual process of obtaining informed consent from potential participants could vary significantly both within and across studies. As a result, approaches to delivering informed consent may range from allowing participants to review the information independently (e.g., via electronic consent) to actively engaging them in face-to-face discussions—sometimes supported by visual or multimedia aids—to enhance comprehension and support informed decision-making.[10]

Additionally, another study underscored that despite the recognized importance of the informed consent process in clinical research, its effectiveness and validity are frequently questioned. The author noted that in many settings, there is limited emphasis on ensuring participants' true comprehension and voluntary participation, and that the informed consent process often becomes a symbolic act rather than a meaningful ethical safeguard.[11]

A study involving a clinical trial participants suggested that individuals should be actively engaged in discussions about their views on the informed consent document. This approach reinforces the concept of informed consent as an ongoing process, rather than a one-time act focused solely on written information.[12] In the present study, the authors implemented an educational intervention consisting of tarpaulins, a one-page brochure, and a short interactive lecture to enhance awareness of the research participants' bill of rights.

The second issue relates to the need for data collection among participants in rural study sites, such as those included in this study, with the aim of reducing disparities in healthcare. A community-based research study highlighted that one major barrier to addressing health disparities is the inadequate recruitment of underserved populations, which limits the development of culturally-tailored interventions. Additionally, the creation of clear and inclusive research guidelines can help improve recruitment of underserved groups, ultimately contributing to the reduction of health disparities and the achievement of health equity for all.[13]

In fact, a study noted that research on the informed consent process has shown that participants may not fully understand the study they are enrolled in, nor their rights as participants, even after signing a consent form. Misunderstandings may be more common in settings where participants are economically disadvantaged, have limited literacy, are unfamiliar with medical research, or hold different cultural views on health and disease.[8] This was reflected in the results of this study, where unemployed individuals—as well as those with limited employment opportunities, such as women, older adults, and those who did not complete high school—demonstrated lower awareness of the bill of rights, even after the educational intervention.

The study further noted that challenges related to informed consent may be more pronounced in certain settings where participants face difficulties with study compliance, limited ability to assess clinical trial risks, fear of procedures, and concerns about reduced access to medical care.[8] These issues can adversely affect the conduct of clinical research, especially in contexts

burdened by limited resources, weak infrastructure, and low literacy levels. Addressing these challenges may require strategic interventions from researchers, sponsors, and regulatory authorities.

A similar line of reasoning was presented in a study, which emphasized the growing international recognition that populations included in clinical trials should adequately reflect those treated in actual clinical practice.[14] Since the study population resides in a rural community and was recruited to participate in clinical research, it is imperative that they were made aware of the research participants' bill of rights.

Another study agreed that obtaining informed consent from vulnerable populations remains a complex issue. It emphasized that a friendly and approachable process is essential to adequately engage these groups, suggesting that accessible locations such as health centers or community buildings can facilitate participation.[15] In the present study, the village multi-purpose hall served as the venue for research activities. Notably, the full cooperation, support, and presence of local authorities during data collection were also ensured.

A systematic review affirmed that community engagement is essential, particularly when the role of family and community leaders in decision-making is acknowledged and incorporated. Community engagement addresses the importance of perceived personal and/or community benefit in the decision to participate in research and can enhance participants' understanding of the study.[16]

Likewise, a study involving ethnic or minority communities emphasized that certain populations remain underserved by research, leading to lower inclusion rates, under-researched health issues, and insufficient consideration of how different communities respond to health interventions. Minoritized ethnic groups often face health inequalities and significant barriers to accessing health services.[17] In the present study, gathering responses from adults in a rural municipality helped enhance their awareness of the elements of the research participants' bill of rights, thereby empowering them as potential participants in future clinical trials while also safeguarding their personal autonomy.

A study noted that the process of obtaining informed consent can be particularly challenging when working with vulnerable populations or during public health emergencies such as pandemics. Nevertheless, it emphasized that a comprehensive informed consent process remains essential for ensuring credible and ethical research.[18]

A systematic review on issues related to comprehension during the informed consent (IC) process primarily focused on the challenges that potential participants may encounter in understanding IC documents, as well as the strategies employed to improve comprehension. The review aimed to identify and describe the key factors influencing participants' understanding and to evaluate the effectiveness of various approaches designed to enhance the informed consent process.[19]

A study involving participants from two clinical trials found that many studies in low-resource settings face challenges in obtaining valid informed consent due to structural factors such as poverty and unequal access to healthcare.[20] These societal issues continue to pose difficulties for investigators. The study further noted that while all interviewed participants were aware they were involved in research, their understanding of the research's nature and the details of the clinical trials varied widely.[20] In the present study, there was no significant improvement in participants' awareness of the clinical trial activities even after the intervention. This highlights an ongoing challenge for researchers—to strike a balance between providing comprehensive yet easily understandable explanations of the clinical research or trial objectives.

In fact, a study involving participants in a biobanking platform highlighted the importance of engaging communities to develop contextually relevant terminologies that participants can easily understand. The researchers emphasized the need to consider the socio-economic context of communities, cautioning that compensation—while important—may become coercive if not appropriately managed.[21]

Similarly, a community-based study found that the unique ethnic, socioeconomic, and cultural diversities in such settings pose important implications for the informed consent process. These include challenges related to individual decisional autonomy, beneficence, confidentiality, and the act of signing the consent document.[22]

A malaria vaccine trial conducted in Mali, West Africa revealed substantial disparities in comprehension between urban and rural participants: 85% of urban participants understood that participation was voluntary, compared to only 21% of rural

participants.[23] These findings underscore how limited access to education and health information in rural, resource-limited settings can hinder understanding of key elements of informed consent. In contrast, a study in Ontario, Canada, found that 18% of participants admitted to not fully reading the study information document, and 10% reported being afraid to ask questions.[24] These barriers were attributed not to lack of access, but to factors such as overly lengthy and complex consent documents, time pressures during the consent process, and emotional factors such as anxiety. Taken together, these studies highlight that while structural barriers dominate in low-resource settings, psychological and procedural factors may limit informed consent comprehension even in high-resource contexts.

Another vaccine trial conducted in South Africa examined participants' recall and understanding of the components of informed consent. The study found moderate levels of recall and understanding overall, with most participants aware of the risks involved and their voluntary participation. Notably, those with at least a Grade 7 education were significantly more likely to demonstrate higher recall scores compared to those with less education.[25]

As previously noted, a study involving participants in a malaria vaccine trial in Mali, West Africa, revealed that many respondents had difficulty understanding key aspects of the research, such as the right to withdraw, the possibility of side effects, and the distinction between participating in a study versus receiving standard therapy. Comprehension was generally better in the village located nearer to an urban center than in the more remote rural village.[23] Similarly, the village in this study is rural, though not geographically isolated, and participants had relatively better access to information. Following the educational intervention, participants demonstrated improved awareness of key elements of informed consent—paralleling the findings in the less remote village from the Mali study.

The present study identified certain characteristics among potential research participants that may require additional interventions to ensure meaningful informed consent. These include being female, middle-aged or older, having lower educational attainment, and being unemployed. Notably, individuals with these characteristics are often the most accessible participants for community-based clinical trials. This underscores the importance of clearly emphasizing the elements outlined in the participant's bill of rights, in addition to the standard informed consent document. These were also found in a study which found that socio-demographic and economic factors—such as older age, limited education, female gender, and low socioeconomic status—were associated with a diminished quality of the informed consent process.[26]

On one hand, a study involving parents of children enrolled in a prospective cohort study emphasized that, to generate generalizable results and ensure a fair distribution of research risks and benefits, researchers should not exclude underprivileged individuals from participation without valid reason.[27] Therefore, it is essential to thoroughly analyze the characteristics of potential research participants when recruiting for clinical trials, in order to identify factors that may negatively impact the quality of informed consent.[26]

The authors of this paper chose to focus on awareness, as opposed to understanding, due to the extensive body of literature consistently highlighting challenges associated with the understanding component of decision-making in research participation. A 2001 study noted the absence of a standardized approach for measuring understanding, despite various efforts to develop appropriate assessment tools.[1] True understanding of a treatment or research protocol requires that participants receive, encode, retain, and cognitively process the information—tasks that demand a complex interplay of attention, memory, and cognitive function.

Additionally, it has been noted that evaluating a participant's perspective on clinical trials is inherently difficult, as there is no standardized method to accurately measure participant understanding of the information provided.[11]

A study further contends that although participants often do not fully understand the information disclosed during the consent process, there is no established standard for significantly improving this issue. Moreover, attempts to enhance understanding through alternative communication methods and improved consent forms have yielded mixed results. One of the most effective strategies identified is having a study team member or a neutral educator spend more time engaging with participants one-on-one.[27]

In summary, while the informed consent document incorporates all the required principles of research, it can often become overly detailed and lengthy in

its description of the research protocol. In contrast, the research participant's bill of rights presents core elements that are universally applicable, regardless of the type or topic of the clinical research or trial.

The introduction of the research participants' bill of rights at a rural study site made the focus on assessing awareness a logical choice, particularly in light of the challenges surrounding the measurement of understanding as highlighted in the literature.

Conclusion and Recommendation

Following the educational intervention, there was a significant increase in participants' awareness of the elements outlined in the research participants' bill of rights.

Based on these findings, we recommend that a separate document outlining the clinical trial participants' bill of rights be presented, thoroughly explained, and signed by all potential participants prior to their signing of the trial's informed consent form. Additional time for discussion should be allotted for individuals who are older, have not completed high school, are women, or are unemployed. While these groups are often the most accessible in terms of availability and willingness to join clinical trials, the present study found that they continued to demonstrate limited awareness of the bill of rights' elements even after the educational intervention.

Acknowledgment

This paper received funding from the Research Institute for the Health Sciences, UERMMMCI. The authors' personal gratitude to Dr. Vinna Marie Quiñones for the assistance as well.

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