

Original Article

Recall of Consent Information by Day Care Prostate Biopsy Patients: An Assessment of the Role of a Third-party Check

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Received:
16-May-2018;
Revision:
12-Dec-2019;
Accepted:
09-Jan-2020;
Published:
11-Jun-2020

ABSTRACT

Background: To evaluate the extent of recall of consent information by daycare prostate biopsy patients in our low-literacy setting. And to evaluate the role of a 3rd party check on patient's recall of consent information. **Subjects and Methods:** As part of our standard of care, a formal informed consent session for day care prostate biopsy takes place 3 days prior to the procedure. For this study, before leaving the outpatient clinic the same day, the patient acknowledged before a third-party that his concerns were or were not satisfactorily addressed. The extent of recall of consent information was assessed on the morning of the procedure using a researcher-administered questionnaire. Consecutive patients participated in this cross-sectional study for day care prostate biopsy at a tertiary hospital in southeast Nigeria from February to November 2015 after obtaining due consent. **Results:** The recall of the risks associated with the planned procedure was poorer than the recall of the nature of the disease condition or the nature of the planned procedure. However, it was observed that aggregate recall was significantly poorer among patients who negatively attested to a satisfying consent session (OR 0.125; $P < 0.0005$). **Conclusion:** The use of a third-party in determining patient satisfaction after a consent session may be a better indicator of patient comprehension and subsequent recall of consent information, especially in low-literacy settings. Using a third-party, in this manner, may assist in checking paternalism inherent in the patient-doctor relationship.

KEYWORDS: *Consent-information recall, patient satisfaction, prostate biopsy, third-party check*

INTRODUCTION

Any surgical procedure plays a significant event in a patient's life and is perceived to be associated with risks by all stakeholders. Some procedures, however, are undertaken as day care procedures based on the understanding that the patients have minimal risk of significant post-procedure morbidity.^[1-4] A prostate biopsy is one such procedure. The informed consent process in an ambulatory surgical setting similar to that in major nonambulatory surgical settings aims to address all known sources of concerns^[5] for the patients in a bid to allay anxiety.^[6]

Short-term recall of information transmitted during the consent process about the planned procedure is known to be generally low, even among patients scheduled

for minor procedures.^[7] To date, the extent of recall of consent information by the patient remains a recognized approach to assess understanding of the proposed treatment procedure,^[8] and in this regard, various strategies have been deployed in attempts to increase the extent of the recall by patients.^[9,10]

Irrespective of the strategy used, it is advocated that personalized communication, in contrast to top-down exposition or standardized interactions, should take

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How to cite this article: Nnabugwu II, Ugwumba FO, Udeh EI, Anyimba SK. Recall of consent information by day care prostate biopsy patients: An assessment of the role of a third-party check. Niger J Clin Pract 2020;23:754-8.

Access this article online

Quick Response Code:	Website: www.njcponline.com
	DOI: 10.4103/njcp.njcp_233_18

place between the physician and the patient to maximize patient understanding.^[11,12] We propose that the patient's opinion on how satisfactorily their concerns were addressed could be sought for shortly after the informed consent process by a third-party who was not part of the consent session. This simple strategy which can easily be applied in our low-literacy, the low-income setting may give the patient the opportunity of expressing their satisfaction with the consent communication thus, reducing paternalism and information overwhelm.^[13,14]

A personal acknowledgment by the patient to a third-party that the information received was satisfactory and has addressed all concerns may reflect that comprehension has taken place. This strategically positioned question is underpinned by the concept of "hearing the patient's voice"^[11] and adopting the "empathic patient-centered approach towards obtaining informed consent."^[15]

This study shows the relationship between the patient's response to a third-party question on how satisfying the consent process was and the extent of recall 72 h later of the information transmitted during that consent process.

MATERIALS AND METHODS

This is a survey conducted from February to November 2015 in a third-tier hospital, University of Nigeria Teaching Hospital, Enugu Nigeria. The target population was patients undertaking day care prostate biopsy. To be eligible to participate in this study, the patient must have been cognitively sound enough to have given their clinical history themselves and have given informed consent to participate in the study.

As part of the standard of care, procedure-specific informed-consent sessions were conducted by a senior member of the surgical unit during the outpatient clinic visit preceding the procedure day. Before leaving the outpatient clinic on that day, a junior member of the surgical unit enquired of how satisfying the consent information was from the patient. The patient's response to this inquiry was documented as "satisfactory," "unsatisfactory," or "unsure." However, during data analysis, a "satisfactory" response was taken as "positive attestation" while "unsatisfactory" and "unsure" responses were taken as "negative attestation."

On the morning of the surgical procedure day, usually, 3 days after the consent session in the outpatient clinic, Generalized Anxiety Disorder 7 (GAD-7) questionnaire^[16-18] was administered to each participating patient. Those with no or mild anxiety by the GAD-7 score completed our consent information recall questionnaire. Our consent information recall questionnaire was designed to assess the patient's recall of the nature of the disease condition, the nature

of the planned procedure and the risks involved in the planned procedure. The questions were non-leading and open-ended. Two intern doctors, who were previously tutored, also participated in the procedure consent process assisted with the administration of the questionnaires.

Responses to the questions were recorded as "uninformed," "forgotten," "incorrect response," and "correct response." The responses to the three questions from each participating patient were aggregated to create an index of effective consent termed "returns on consent information." This index was ranked into "good returns," "fair returns," and "poor returns." Regression analysis was used to evaluate the relationship between these levels of return on consent information and other variables. Statistical Package for Social Sciences (SPSS) version 20 was used for analysis.

RESULTS

A total of 95 respondents scheduled for day care prostate biopsies participated in this survey. They were 98.9% Nigerians from the southeast region, and within the age group of 55 and 82 years (mean: 68.6 ± 6.2 years). All the respondents checked in no or mild anxiety using the GAD-7 scale with a range of 0–9 and a median of 1 and a mode of 0. Other descriptive statistics are shown in Table 1.

Matching the group that positively attested their concerns were satisfactorily addressed (Group A) against those that negatively attested (Group B) showing no significant differences in level of formal education attained (χ^2 2.822; $P = 0.14$), in comparison of mean age (t -0.684; $P = 0.50$), and in comparison of GAD-7 score (t -0.667 $P = 0.33$).

Figure 1 compares the extent of recall of the information on the nature of disease condition, nature of the planned procedure, and risks involved in the planned procedure by study participants within the two groups.

The calculated index of effective consent shows that 21.1% of participating patients demonstrated good returns on consent information, 44.2% demonstrated

Table 1: Displays the frequency distribution of the responses from study participants

Variable	Value
Post-primary level of formal education	71 (74.7%)
Attested to having received a satisfying consent session	61 (64.2%)
Appropriate recall of nature of disease condition	72 (75.8%)
Appropriate recall of nature of the planned procedure	52 (54.7%)
Appropriate recall of risks involved in a planned procedure	15 (15.8%)

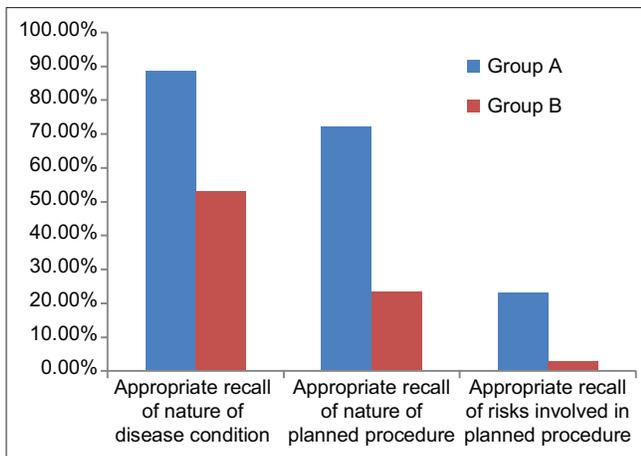


Figure 1: Displays the proportion of appropriate recall by participants within the two groups A and B

Table 2: Displays the results of ordinal regression analysis of the studied variables as they relate to the calculated index of effective consent termed “returns on consent information”

Variables	OR	95% CI	Wald χ^2	P
Age	1.025	0.966-1.088	0.666	0.41
GAD-7	0.974	0.771-1.230	0.050	0.82
Little or No Formal Education	0.640	0.249-1.643	0.861	0.35
Negative Attestation	0.125	0.049-0.318	19.086	<0.0005

[OR: Odds Ratio; CI: Confidence Interval; χ^2 : Chi-square]

fair returns while 34.7% demonstrated poor returns on consent information. Table 2 shows the result of the ordinal regression analysis of the variables that relate to returns on consent information.

DISCUSSION

The concept of a patient’s recall of information transmitted during the consent process has been variously studied. Consistently, the extent of recall has been documented to be low,^[7] the medico-legal implication of which is worrisome for the medical care provider. In view of this, various modalities have been incorporated into the informed consent process to enhance information delivery and comprehension by the patient. These modalities include, although are not limited to handing out information bills and documents,^[19] use of patient-friendly multimedia materials^[20-22] and repeat back techniques.^[23,24] While some studies have documented objective improvement in the extent of recall of information by patients employing these modalities,^[19,20,22,25] others have failed to establish the same.^[26,27]

Our low-socioeconomic setting is challenged by low-literacy levels, less than optimal infrastructure

development, poor language development (making the translation of consent information to the local languages challenging), absence of social security, and rudimentary health insurance system.^[28,29] Handing out complimentary patient information leaflets to be studied at home and the playback of patient-friendly multimedia recordings during consent proceedings are of limited use in our practice due to the aforementioned challenges. Therefore, the search is still on for means of improving patients’ extent of recall of information transmitted in the course of obtaining informed consent from patients for any diagnostic or therapeutic intervention.^[30]

In this study, we evaluated the implications of a simple but resource-poor-compliant strategy termed “third-party check.” We introduced the interposition of a member of the medical care team who was not part of the informed consent process, between the consent process and the administration of the planned procedure. This interposed member simply asked whether the patient’s concerns were satisfactorily addressed, from the patient’s perspective, during the consent process or not. The step is akin to the concept behind the advocated personalized or empathic patient-centered consent.^[11,15]

Overall, 75.8% of the respondents were able to appropriately recall the information on the nature of diagnosis [Table 1] which is quite impressive. On the background that 74.7% of the respondents had formal education beyond the primary level [Table 1], this proportion of respondents that appropriately recalled the nature of diagnosis could be understood. The improved understanding and hence, recall of consent information associated with formal education and health literacy has been reported.^[31,32] However, just 15.8% of respondents demonstrated appropriate recall of risks involved in the planned procedure. Johnstone *et al.*^[32] also observed poor recall of risks or complications of the planned procedure. This recall pattern may be because study participants shut out information on risks or complications to avoid being overwhelmed by consent information.

Figure 1 shows that participants that attested positively that the consent process was satisfying, demonstrated better recall across all domains. This finding is similar to that of Nehls *et al.* in Berlin which shows that higher satisfaction with consent communication is associated with the higher recall of consent information.^[33] Due to paternalism in patient-doctor interactions particularly in low-literacy settings, it is usual for the doctor to elicit a near 100% patient agreement with the consent information,^[34] only for the patient to express some concerns to a third-party in the absence of the doctor. From this study, only 64.2% of the participating patients [Table 1] positively attested to a third party that

their concerns were indeed satisfactorily addressed by the consent process.

The calculated index of effective consent which is an aggregation of the appropriateness of patient's recall in the three assessed domains showed that 34.7% of respondents demonstrated poor returns on consent information. More specifically, there are a 0.125 odds (95% CI 0.049–0.318; Wald χ^2 19.086; $P < 0.0005$) that a respondent attested negatively to the consent process would demonstrate fair or good returns on consent information. The other variables studied [Table 2] did not significantly influence returns on consent information. A similar observation had been made by other studies.^[33,35] Every consent session must be satisfying from the patient's perspective. The doctor or the provider of the consent information may not be the most appropriate person to determine from the patient or information receiver that the latter's concerns have been well addressed.

CONCLUSION

The recall of consent information on nature of disease condition, the nature of the planned procedure, and the risks involved in the planned procedure are significantly higher among patients that positively attested to a third-party that the consent processes satisfactorily addressed all their concerns irrespective of age and formal educational attainment of the patients.

Practice implications

Clinically, the finding from this study can be of relevance in the process of obtaining informed consent from patients before any diagnostic or therapeutic procedure especially in the low-literacy medical practice. Conventionally, the patient signs the consent form after admitting to the physician that their concerns have been satisfactorily addressed. In our low-literacy setting, this may be pro-paternalistic. With the third-party check as proposed, the patient is "freer" to exercise his autonomy such that patient satisfaction is consequent upon better understanding.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

- Mahboubi H, Verma SP. Ambulatory laryngopharyngeal surgery: Evaluation of the national survey of ambulatory surgery. *JAMA Otolaryngol Head Neck Surg* 2013;139:28-31.
- Dulfer RR, van Ginhoven TM, Geilvoet W, de Herder WW, van Eijck CH. Operative treatment of primary hyperparathyroidism in daycare surgery. *Scand J Surg* 2015;104:196-9.
- Agbakwuru EA, Faponle AF, Adesunkanmi AR, Ogundoyin O. Practice and acceptance of day-care surgery in a semi-urban Nigerian hospital. *East Afr Med J* 2001;78:170-3.
- Ojo EO. Day case surgery and developing countries: A review. *Niger J Clin Pract* 2010;13:459-66.
- Sarkar R, Sowmyanarayanan TV, Samuel P, Singh AS, Bose A, Muliyl J, *et al.* Comparison of group counseling with individual counseling in the comprehension of informed consent: A randomized controlled trial. *BMC Med Ethics* 2010;11:8.
- Dawes PJ, O'Keefe L, Adcock S. Informed consent: The assessment of two structured interview approaches compared to the current approach. *J Laryngol Otol* 1992;106:420-4.
- Pathak S, Odumosu M, Peja S, McIntyre K, Selo-Ojeme D. Consent for gynaecological procedure: What do women understand and remember? *Arch Gynecol Obstet* 2013;287:59-63.
- Nnabugwu II, Ugwumba FO, Udeh EI, Anyimba SK, Ozoemena OF. Informed consent for clinical treatment in low-income setting: Evaluating the relationship between satisfying consent and extent of recall of consent information. *BMC Med Ethics* 2017;18:69.
- Olsen BT, Sherwood CJ, Carrico CK, Priest JH, Laskin DM. Patient recall of information on a third molar informed consent video. *J Oral Maxillofac Surg* 2017;75:2507-11.
- Mboizi RB, Afolabi MO, Okoye M, Kampmann B, Roca A, Idoko OT. Recall and decay of consent information among parents of infants participating in a randomized controlled clinical trial using an audio-visual tool in The Gambia. *Hum Vaccin Immunother* 2017;13:2185-91.
- Holt B, Boudier F, Elemuwa C, Gaedicke G, Khamesipour A, Kisler B, *et al.* The importance of the patient voice in vaccination and vaccine safety – Are we listening? *Clin Microbiol Infect* 2016;22(Suppl 5):S146-53.
- Heisig SR, Shedden-Mora MC, Hidalgo P, Nestoriuc Y. Framing and personalizing informed consent to prevent negative expectations: An experimental pilot study. *Health Psychol* 2015;34:1033-7.
- Jansen LA, Wall S. Reconsidering paternalism in clinical research. *Bioethics* 2018;32:50-8.
- Bester J, Cole CM, Kodish E. The limits of informed consent for an overwhelmed patient: Clinicians' role in protecting patients and preventing overwhelm. *AMA J Ethics* 2016;18:869-86.
- Pereira L, Figueiredo-Braga M, Carvalho IP. Preoperative anxiety in ambulatory surgery: The impact of an empathic patient-centered approach on psychological and clinical outcomes. *Patient Educ Couns* 2016;99:733-8.
- Mitchell AJ, Morgan JP, Petersen D, Fabbri S, Fayard C, Stoletniy L, *et al.* Validation of simple visual-analogue thermometer screen for mood complications of cardiovascular disease: The Emotion Thermometers. *J Affect Disord* 2012;136:1257-63.
- Wenham CY, Conaghan PG. Optimising pain control in osteoarthritis. *Practitioner* 2010;254:23-6.
- Taube-Schiff M, Van Exan J, Tanaka R, Wnuk S, Hawa R, Sockalingam S. Attachment style and emotional eating in bariatric surgery candidates: The mediating role of difficulties in emotion regulation. *Eat Behav* 2015;18:36-40.
- Clarke K, O'Loughlin P, Cashman J. Standardized Consent: The Effect of Information Sheets on Information Retention. *J Patient Saf* 2018;14:e25-e28.
- Yin B, Goldsmith L, Gambardella R. Web-based education prior to knee arthroscopy enhances informed consent and patient knowledge recall: A prospective, randomized controlled study.

- J Bone Joint Surg Am 2015;97:964-71.
21. Farrell EH, Whistance RN, Phillips K, Morgan B, Savage K, Lewis V, *et al.* Systemic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice. *Patient Educ Couns* 2014;94:20-34.
 22. Siao D, Sewell JL, Day LW. Assessment of delivery methods used in the informed consent process at a safety-net hospital. *Gastrointest Endosc* 2014;80:61-8.
 23. Prochazka AV, Fink AS, Bartenfeld D, Henderson WG, Nyirenda C, Webb A, *et al.* Patient perceptions of surgical informed consent: Is repeat back helpful or harmful. *J Patient Saf* 2014;10:140-5.
 24. Festinger DS, Dugosh KL, Malowe DB, Clements NT. Achieving new levels of recall in consent to research by combining remedial and motivational techniques. *J Med Ethics* 2014;40:264-8.
 25. Afolabi MO, Bojang K, D'Alessandro U, Imoukhuede EB, Ravinetto RM, Larson HJ, *et al.* Multimedia informed consent tool for low literacy African research population: Development and pilot testing. *J Clin Res Bioeth* 2014;5:178.
 26. Khan Z, Sayers AE, Khattac MU, Eastley NC, Shafqat SO. A prospective randomized control study on patients recall of consent after hand surgery: How much they want to know? *Orthop Rev (Pavia)* 2013;5:e32.
 27. Naini P, Lewis J, Rajanna K, Weir AB 3rd. Evaluation of a method to improve the consent process: Improved data retention with stagnant comprehension. *J Cancer Educ* 2013;28:38-42.
 28. Krosin MT, Klitzman R, Levin B, Cheng J, Ranney ML. Problems in comprehension of informed consent in rural and peri-urban Mali, West Africa. *Clin Trials* 2006;3:306-13.
 29. Chima SC. "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa. *Niger J Clin Pract* 2015;18(Suppl):S46-56.
 30. Wang DS, Jani AB, Tai CG, Sesay M, Lee DK, Goodman M, *et al.* Severe lack of comprehension of common prostate health terms among low-income inner-city men. *Cancer* 2013;119:3204-11.
 31. Ownby RL, Acevedo A, Goodman K. Health literacy predicts participant understanding of orally-presented informed consent information. *Clin Res Trials* 2015;1:15-9.
 32. Johnstone M, Harlamb S, Parashos P. Recall and understanding of risk in endodontics: A questionnaire survey. *J Law Med* 2016;23:637-49.
 33. Nehls W, Gabrijel S, Kiss A, Kollmeier J, Schmalz O, Albrecht H, *et al.* Physician communication in a lung cancer center—Does the message come across? *Pneumologie* 2013;67:688-93.
 34. Hajivassiliou EC, Hajivassiliou CA. Informed consent in primary dental care: Patients' understanding and satisfaction with the consent process. *Br Dent J* 2015;219:221-4.
 35. Howard N, Cowan C, Ahluwalia R, Wright A, Hennessy M, Jackson G, *et al.* Improving the consent process in foot and ankle surgery with the use of personalized patient literature. *J Foot Ankle Surg* 2018;57:81-5.