

INFORMED CONSENT: THE RADIOLOGIST ADMINISTERING RADIOLOGICAL
CONTRAST MEDIA

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ABSTRACT

This study represents the understanding and practice of radiologists in Nigeria in obtaining informed consent from patients before administering radiological contrast media.

120 questionnaires were sent to radiologists practicing in Nigeria. 78(65%) responded, 60(76.9%) of the respondents understood informed consent to mean informing a patient about a procedure and obtaining consent to carry out the procedure. Whereas for consent to be informed it must include the nature of the procedure, purpose, risks and benefits. 52(66.7%) obtained either written or verbal consent while 26(33.3%) neither informed patient nor obtained consent. However, all respondents understood that failure to obtain consent may result in possible litigation by patient or relative while 69(88.5%) requested for a specific policy regarding informed consent.

It is concluded that the radiologist in Nigeria does not fully understand the concept of informed consent. A specific policy should be made by the appropriate professional body in Nigeria as to what constitutes the requirements of a truly informed consent since there are simply

no guidelines for now. Also informed consent forms, simple enough for patients to understand should be designed. These will assist the individual specialist in the conduct of their practice.

ABSTRAIT

Cette étude représente l'arrangement et la pratique des radiologistes au Nigéria en obtenant le consentement informé des patients avant d'administrer des médias de contraste radiologiques.

120 questionnaires ont été envoyés aux radiologistes pratiquant au Nigéria. 78(65%) répondu, 60(76.9%) des répondants a compris le consentement au courant pour signifier informer un patient au sujet d'un procédé et obtenir le consentement pour suivre le procédé. Considérant que pour que le consentement lui soit informé doit inclure la nature du procédé, but, risques et avantages. 52(66.7%) n'a obtenu consentement écrit ou verbal tandis que 26(33.3%) ni patient au courant ni consentement obtenu. Cependant, tous les répondants ont compris que le manque d'obtenir le consentement peut avoir comme conséquence le litige possible par le patient ou le parent tandis que 69(88.5%) demandait pour une politique spécifique concernant le consentement

au courant.

On le conclut que le radiologiste au Nigéria ne comprend pas entièrement le concept du consentement au courant. Une politique spécifique devrait être définie par le corps professionnel approprié au Nigéria quant à ce qui constitue les conditions d'un consentement véritablement au courant puisqu'il n'y a simplement aucune directive pour maintenant. Formes en outre informées de consentement, assez simple pour que des patients comprennent devraient être conçus. Ceux-ci aideront le spécialiste individuel dans la conduite de leur pratique.

INTRODUCTION

The rights to be informed or not about health and intervention is a patient's personal right, disregarding these rights may give rise to legal liability on the part of the physician.¹ The use of informed consent before intravenous administration of radiological contrast media (RCM) remains a controversial issue. Non radiologists were more likely to obtain informed consent before the use of RCM than Radiologists.²

With the steady increase in the literacy level of the general populace in Nigeria, patients expectation are higher regarding information, safety and security of diagnosis. There is also an increasing diversity of imaging technology, an increasing number of perhaps over enthusiastic lawyers and an increasing amount of litigation. People are aware of their legal rights even in medical treatment; Radiologists must therefore be alert to the legal environment in which they currently practice.

It is inevitable that any RCM whether administered appropriately or not will occasionally cause unwanted adverse drug reactions which may eventually become the subject of medical litigation.³

The consent of the patient is only legally binding when he has been informed in advance of the objectives, extent, necessity, urgency, type, procedures and alternatives of a medical investigation or therapeutic intervention and also of the accompanying risks.⁴

The patient has the right to withdraw his consent freely at anytime (consent refusal) and treatment without consent or informed consent is a "medical malpractice".¹

In a proper physician-patient relationship, informed consent controversy should be rare.

The aim of this study therefore is to alert the Radiologist in Nigeria on the need to fully understand the concept of informed consent.

MATERIALS AND METHODS

120 questionnaires were distributed to radiologists practicing in private and government owned hospitals in Nigeria. 78 questionnaires were returned. Information obtained include: Type and years of practice, knowledge of medico-legal aspects of radiological procedures, explanation of informed consent, commonest attitude of patients informed, incidence of reaction to contrast media, result of failure to obtain consent.

RESULTS

Types and Years of practice:- 68(87.2%) practiced in government owned hospitals while 10(12.8%) were in private practice both with a range 3 years to 36 years of practicing experience.

Medico-legal Knowledge:- Only 25(32.1%) had knowledge of medico-legal aspect of radiological procedures but all are aware of the stipulated penalties for professional misconduct.

Explanation of Informed Consent:- 60(76.9%) explained informed consent

while 18(23.1%) made no attempt.

Type of Consent:- 37(47.4%) obtained verbal consent, 15(19.3%) obtained written consent and 26(33.3%) obtained none. 52(66.7%) obtained consent just before administration of RCM, 26(33.3%) made no response.

Risk of Disclosure:- 58(74.4%) informed patient of possible mild reactions only, 20(25.6%) disclosed both mild and moderate reactions, major reactions were not disclosed.

Patients Attitude:- Only 18(23.1%) of respondents observed anxiety and fear on patients. No patient refused procedure.

Incidence of Adverse Reactions:- Incidence of reaction to contrast media remained low in all patients and informing the patients had no effect on the number of interventional procedures performed in the department.

Failure to Obtain Consent:- All respondents are aware that this could result in litigation by patient or relative.

Specific Policy:- 69(88.5%) requested for a specific policy regarding informed consent.

DISCUSSION

The doctrine of informed consent derives in part from two principles.

1. A person's inherent right to control what happens to his or her body as annunciated in Justice Cardozo's landmark opinion: - "Every human being of adult year and sound mind has a right to determine what shall be done with his own body".⁵
2. The physician's fiduciary duty to the patient: The physician has the right to warn the patient and the patient

has the right to know what a "reasonable man" would want to know. The patient has no duty to inquire about the risks involved in medical treatment.⁶

Interventional procedure is a medical invasion of a patient's freedom. It does not constitute an offence of causing bodily harm if there is a medical indication, when the patient has given consent after being adequately informed and the intervention carried out in accord with the valid rules of medical conduct.⁴ It is well established and generally acknowledged in the radiology community that radiologists must obtain informed consent from patients before commencing certain diagnostic or therapeutic procedures. During the consent process, the radiologists must divulge to the patient information regarding benefits and risks of performing the procedure.⁷

76.9% of the respondents defined informed consent as informing patient about a procedure and obtaining consent to carry out the procedure. Whereas for consent to be fully informed, five areas are to be addressed:

- (1) The nature of the procedure.
- (2) Purpose.
- (3) Risks.
- (4) Benefits.
- (5) Availability of alternatives to the proposed procedure.

The exceptions to these requirements being:

1. Emergency
2. Incompetence i.e. patient is in no position to give to meaningful consent as in madness or unconsciousness
3. Therapeutic privilege.

On risks disclosure, 74.4% informed patients about mild reactions to RCM

with the hope of obtaining maximum cooperation during the procedure and to allay fear and anxiety. No major reactions were disclosed. The physician believes that the hazard of informing the patient of the risk is greater than the risk itself. The radiologist should bear in mind the fact that all risks on the basis of which a responsible patient can make the decision to consent or reject a specific medical intervention are to be considered as relevant and must be explained immediately.⁴ An attitude of fear and anxiety was noted in patients in this study whereas in a similar study, patients reacted more to the probability of potential contrast reaction than severity.⁸

There is documentation in support the concept that anxiety is associated with an increased incidence of minor or even moderate reactions⁹ but in this study the incidence of RCM reaction remained low even in obviously anxious patients. Patients must be informed well before the procedure; explanations given on the evening before procedure are deemed to be too late except in exceptional circumstances.¹⁰ (which had earlier been mentioned). Meanwhile in this study 66.7% of respondents informed and obtained consent just before the administration of RCM, this was obviously too late. While 19.3% neither informed nor obtained consent and 47.4% had verbal consent, 33.3% neither informed nor obtained consent and no reason was given for this action.

It is important to note that the content of discussions held with patient or relative to obtaining informed consent should be well documented in the patient's chart or radiology report.¹¹ The ever increasing importance of adequate documentation in the light of malpractice proceedings cannot be overemphasized.¹² On the medico-legal aspect of radiological procedures only 32.1% had knowledge.

This may be a pointer as to why 33.3% of the respondents failed to inform or obtain consent from patients. It is suggested that this subject should be introduced into the curriculum in the training of resident doctors in Radiology. All respondents understood the implication of not obtaining consent. Considering the legal environment which the radiologists currently practice and the fact that every activity of a medical practitioner may be subjected to court control¹², it therefore becomes a medical necessity to understand the requirements of informed consent.

Radiologists must attempt to avoid the excesses of defensive medicine while providing optimum diagnostic services, they should remain sensitive to patient's legitimate requirements in this era of rapidly changing, improving and more expensive diagnostic technology. Finally, 88.5% of respondents requested for a specific policy regarding informed consent from their professional body, since the amount of information that should be given to patients before the administration of RCM remains unclear because there are simply no succinct guidelines.

In conclusion, the radiologist in Nigeria does not fully understand the concepts of informed consent. Apart from a specific policy regarding informed consent, consent forms simple enough for patients to understand should also be designed. These will assist the individual specialist in the conduct of their practice.

QUESTIONNAIRE

INFORMED CONSENT: THE RADIOLOGIST ADMINISTERING CONTRAST MEDIA

- i) Hospital Name:.....
- ii) Town:
- iii) Types of Practice: Private () Govt. Owned ()
- iv) Years of experience as a Radiologist:.....

QUESTIONS:

1. Did your training include courses on the Medicolegal aspects of radiological procedures. Yes () No ()
2. Are there stipulated penalties by your professional bodies for misconduct. Yes () No () Not aware ()
3. What do you understand by Informed Consent (briefly explain).
.....
.....
4. What form of consent do you obtain from patients. Verbal () Written () None ()
5. When do you obtain consent to administer contrast medium.
On Booking () Just before procedure () During procedure ()
6. Informed consent is necessary before administering medium in:-
a) All cases () b) Some cases () if b) Give examples,
7. On administering a contrast medium do you inform your patient of possible specific adverse reactions. Yes () No () Sometimes (), If No why.....
8. Which possible reactions do you inform patient.
Mild () Moderate () Severe ()
9. What was the commonest attitude observed in patient.
Anxiety () Consent () Refusal ()
10. For patients who were anxious but still gave their consent, what was the incidence of reaction to contrast media. High () Low () Nil ()
11. Has informed consent lessened the number of interventional procedures performed in your department.
Yes () No () If yes by what %.....
12. Can failure to obtain patients consent result in:- surcharge by your employer () Dismissal by employer () Litigation by Patient/relative ()
13. Would you rather have a specific policy regarding informed consent from your professional body before applying it to patients?
Yes () No ()

THANK YOU

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