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INFORMED CONSENT;
AWARENESS AND PRACTICE AMONG GENERAL MEDICAL PRACTITIONERS

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ABSTRACT… Introduction: Informed consent is the back bone of patients' autonomy. The advancement in medical technology has further increased its importance. In the developing countries including Pakistan, general physicians play a vital role in providing health care to the patients but unfortunately majority of them are unaware about the ethical aspects of their medical practice. **Methodology: Objectives:** 1. To determine the level of awareness about informed consent among general practitioners. 2. To assess the association between various socio-demographic factors to the awareness about informed consent. **Study Design:** Community based cross sectional study. **Settings:** General medical practitioners of district Hyderabad were the study population. **Period Of Study:** Two months. **Material & Methods:** One hundred & forty subjects were selected for the study through purposive non-probability sampling. A pretested self-administered questionnaire was the tool for the data collection. The data was analyzed by using SPSS version 16.The variables of interest were gender of general practitioners, their age, level of qualifications, residence & occasions when informed consent was taken. The association between various socio-demographic variables was determined by applying Chi-square test at ≤0.05 level of significance. **Results:** One hundred & forty general medical practitioners of varying ages from 32-60 years participated in the study. The mean age of the general physician was 39 ± 1.8 years. The awareness about informed consent was found among 128(91.4%) subjects but unfortunately only 45.7%of them actually practiced it. The results regarding awareness as well as practice of informed consent among males and females were however not significant (p=0.520). The young general practitioners i.e age 31-40 years were less practicing informed consent as compared to older general practitioners i.e. age 51-60 years and onwards (p= 0.04).The physicians practicing in urban areas were more cognizant about informed consent (p=0.05).Informed consent from patients was obtained before giving local anesthesia (80%), blood transfusion (24.3%)&before examination of female patients (46.4%). **Conclusions:** Informed consent taking is not a routine process adopted by general medical practitioners so there is a strong need for general practitioners to change their attitude and acknowledge the patient's autonomy by taking informed consent, which is the basis of modern medical ethics.

Key words: Informed Consent, General Practitioners, Patient atanomy.

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INTRODUCTION

The right of patients to make decisions about their medical care without coercion by health care provider is called patients' autonomy. We find the references of patients' autonomy more frequently now days than previous days[1] & it also shows the emerging importance of the patients' autonomy in the coming days. Patients' autonomy cannot be completely fulfilled if he is denied for giving informed consent. Informed consent is a process for getting permission before conducting a healthcare intervention on a person. A health care provider may ask a patient to give consent to receive a medical therapy or a surgical intervention. The process of informed consent not only gives a sort of permission to the health care provider from the patient but it is also a means of confidence building between the twosides.[2] Historically, informed consent is a very old method employed for taking permission from the patient but its legacy styles have been taking very varied shapes with the passage of time.[3] Despite being

a worthwhile practice, informed consent has not been taken seriously sometimes by the care givers & sometimes by the patients themselves especially in the field of psychotherapy.[4] This has been evident even in the situations at community health centers, even in presence of very stringent institutional policies.[5]

In Pakistan health care is being provided through public sector as well as through private sector. The general practitioners are considered as the back bone for the health care delivery system in our country. In the medical profession, a general practitioner (GP) is a medical doctor who although does not qualify / specialize in a particular field but he cares for the general health of the community by treating acute and chronic illnesses and by providing preventive care and health education to patients. Regarding general practitioners' perception about bioethics, it is apparent that although they feel that patients have a right to knowledge about their disease status but a high proportion of general practitioners do not consider it necessary to explain the details of the treatment advised to patients.[5]

On many occasions, it has been noted that the respect for physicians inhibits the individuals from questioning the purpose and benefits of research[6] but still many studies conclude that it was imperative that individuals understand what health information sharing entails.[7] Informed consent is the simplest way of sharing of sufficient medical knowledge by communication between doctor & patient. This is more important in our setting where most of the times, the patients have very wrong concepts about the informed consent.[8]

METHODOLOGY

Objectives

1. To determine the level of awareness about informed consent among general medical practitioners.

2. To assess the association between various socio-demographic factors to the awareness about informed consent.

Study design & Setting

It was a community based cross sectional study conducted on the general medical practitioners of district Hyderabad. Administratively Hyderabad district is divided into Hyderabad urban & Hyderabad rural areas. Hyderabad urban is divided into taluka Qasimabad, City & Latifabad.

Material & Methods

The study population comprised of general practitioners of district Hyderabad. In order to get the representation of all the areas, the data was collected from male & female general practitioners of all the talukas of Hyderabad urban as well as from Hyderabad rural. A total of one hundred & forty subjects were selected for the study through purposive non-probability sampling.

Period of study

Two months.

DATA COLLECTING TOOL

The data was collected after taking consent from the subjects & explaining the aim of the study to them. A pretested self-administered questionnaire was the tool for the data collection.

DATA ANALYSIS

The data, after editing was analyzed by using SPSS version 16. The frequencies of the categorical variables like gender, academic qualifications, residence, occasions when informed consent was taken etc were computed; mean & standard deviation were calculated for the continuous variables like age of the general practitioners. The association between various socio-demographic variables was determined by applying Chi-square test at p-value of ≤ 0.05 level of significance.

RESULTS

One hundred &sixty five subjects were approached for the data collection; one hundred & forty subjects responded; the response rate was 84.9%. The general practitioners of varying ages from 32-60 years participated in the study. The mean age of the general physician was 39 $\pm$ 1.8 years. Among them one hundred(71.4%) were males and forty (28.6%) were female practitioners. Regarding

education only 40(28.6%) doctors had done post-graduation to improve their qualification. Ninety two (65.7%) were the general practitioners who belonged to urban areas as compared to forty eight (34.3%) who were working in rural set-up. Among the study subjects, 56(40%)were in-service also & were doing private practice in their spare time; while remaining 84(60%) were exclusively doing private practice. Majority 101 (72.1%) were involved in doing general practice & only 39 (27.9%) were doing consultation.

The study revealed tendency of doing general practice among those who did only graduation (p=0.00).The main objective of the study was to get the level of awareness about informed consent among study subjects. Surprisingly, level of awareness was found among 128(91.4%) but unfortunately it was practiced by only sixty four (45.7%); while remaining seventy six (54.3%) were totally not practicing it (Chart-1).

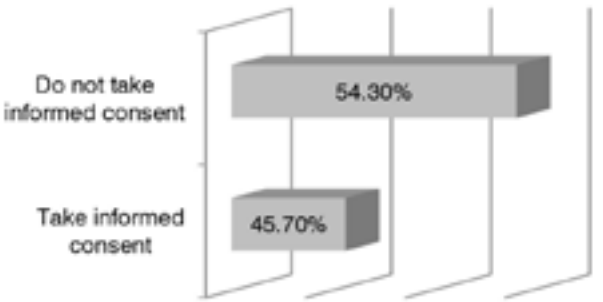

Chart-1. Distribution of general practitioners regarding taking informed consent

The results regarding awareness as well as practice of informed consent among males and females were however not significant (p=0.520) (Chart-2).

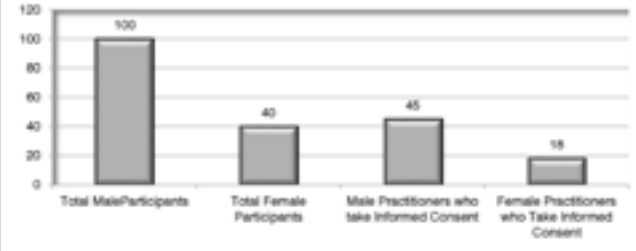

Chart-2. Gender distribution of general practitioners

The young general practitioners i.e age 31-40 years were less practicing informed consent as compared to older general practitioners i.e. age 51-60 years of onwards (p= 0.04). (Chart-3).

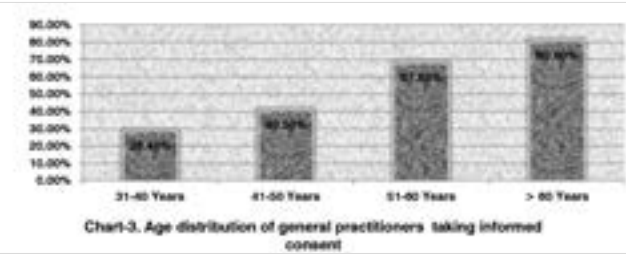

Chart-3. Age distribution of general practitioners taking informed consent

The physicians practicing in urban areas were more cognizant about informed consent (p=0.05).There was a statistically significant association between this practice among highly educated & only graduate physicians (p=0.03). Only 7(5%) practitioners preferred to take consent before giving treatment to the patients. Injectable medicines were also given without consent by many of doctors i.e.90 (64.3%). Only 50 (35.7%) got consent from their patients before giving any injection. Even the post-graduates were not taking any consent before treatment (p=0.086). Giving awareness about complications of medicines or procedures was also not practiced by majority 86 (61.4%). In contrast to this, 54 (38.6%) general practitioners routinely informed the patients about any complication expected to arise from treatment prescribed to the patients.

One hundred & twelve (80%) subjects reported to get consent from patients before giving local anesthesia; this figure was 100% in case of those general practitioners who had done post-graduation in any specialty (p=0.00).Informed consent was taken by only 34 (24.3%) of the general practitioners before blood transfusion to the patients. Sixty five (46.4%) general practitioners favored to take informed consent while examining the females for general ailment or for gynecological problems.

DISCUSSION

The informed consent is an universally recognised procedure to ensure safeguarding the patients' rights.[9] It is now throughout the world that the

requirement for an informed consent is well established in all decision making situations in the clinical practice. It is a well-established fact now days that a fully informed patient can participate in choices about his/her health care.[10]Being a developing country, Pakistan still lacks in some of the crucial health innovations; the informed consent of the patient prior to some medical or surgical intervention is one of them. The informed consent was reported to be demanded only 20% of the patients seeking health care in Karachi.[5]

Keeping in view all these facts, the current study was conducted to get an estimation of the level of awareness about informed consent among general practitioners. The know how about the informed consent was revealed to be among 91.4% of the subjects interviewed but only sixty four (45.7%) of them were actually practicing it; while remaining seventy six (54.3%) were totally ignoring it in their practice. The results about this awareness among males and females were however not significant (p=0.520). Giordano J in the year 2004 also revealed the same situation in developing countries[11].

The physicians practicing in urban areas were more cognizant about informed consent (p=0.05). The level of this practice increased to statistically significant levels when a difference was explored between highly educated & graduate physicians (p=0.03). This may be due to the fact that in urban areas, general practitioners were more exposed to variety of the situations where they entailed informed consent as necessary; moreover, the improvement in qualifications boosted their level of awareness.

A similar study by Bin Briek AS & others also showed the similar results showing a steady rise in positive behavior of family physicians towards their profession as their level of qualification increased.[12] To explore more, the study subjects were also separately asked about the occasions when general practitioners thought necessary to take consent. It was found that only 7 (5%) of the practitioners used to take consent before giving treatment to the patients as compared to 133 (95%) who didn't inform patients about the treatment advised. This was in contrast to fact revealed by Cohen S that to obtain informed consent from patients before initiating any treatment was reported as one of the basic ethical duties in health care.[13]

A study on medical students by Zafar S et al revealed that although 90% of the subjects agreed that written consent was necessary before surgery, only a little more than half of the students thought that discussion about the other options of treatment/ risks of the surgery were appropriate during the process of taking consent[14]. Our study showed that even injectable medicines were being given without consent by many of doctors i.e.90 (64.3%). Only 50 (35.7%) opted to get the consent of the patient before giving any injection. That was an alarming situation because even the post-graduates were not taking any consent before treatment (p=0.086). Giving awareness about complications of medicines or procedures was also not practiced by majority 86(61.4%), In contrast to this, 54(38.6%) general practitioners did routinely inform the patients about any complication arising from treatment prescribed to them. Regarding giving local anesthesia for some minor procedure like dental extraction, applying stitches etc, 112 (80%) reported to get consent from patients; this figure was 100% in case of those general practitioners who had done post-graduation in any specialty (p=0.00).The study by Zafar S et al on this aspect of informed consent showed that the choice of anesthesia was discussed with the concerned patient on 45.3% of the occasions.[14]

Blood transfusion is considered as a basic life saving tool in many medical emergencies. The current study revealed that out of 140 doctors only 34 (24.3%) were of the opinion to take consent for blood transfusion from patients whereas 106 (75.7%) rejected the idea of taking informed consent in case of blood transfusion. This finding is just similar to another research on this issue which showed majority of the practicing physicians considering life saving intervention including blood transfusion without consent

as justified.[15]Lot of work has been done on the medical practices that violate the patients' rights and patient safety by denying information to them while proceeding for some life saving option on the patients.[16]The current study revealed that while examining the females for general ailment or for gynecological problem, the consent was not taken by 75 (53.6%); while 65 (46.4%) general practitioners favored to take informed consent while examining the females. Contrary to this, P Laufer-Ukeles advocated the taking of consent from the women even for their reproductive choices.[17]Denying female patients for the consent could be due to the fact that a large proportion of emergency patients felt frightened or under pressure when signing the form as was concluded by Akkad, Andrea, et al.[18]This could be due to the fact that the obstetrics and gynecology patients were unaware of the legal implications of their opinions &written consent.[19] We found a lack of communication between general practitioners & their patients that needs to be improved Nievelstein et al also concluded in a research on this issue that efforts should be directed towards improved information and communication between the doctors & patients for the betterment of the patients.[20]

CONCLUSIONS & RECOMMENDATIONS

The practice of taking informed consent from patients while treating them is not a very common phenomenon among general practitioners despite the fact that majority of the practitioners have adequate knowledge about it. The results of current study emphasize the need for general practitioners to change their attitude and acknowledge the patient's autonomy by taking informed consent, which is the basis of modern medical ethics.

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"To improve is to change;
to be perfect is to change often."

Winston Churchill

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
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2	Dr. Champa Sushel	Finalizing questionnaire, data collection & literature search	
3	Dr. Shazia Rahman Shaikh	Making questionnaire, doing editing & analyssi of data & compilation of results	
4	Dr. Fahad Ahmed Memom	Literature search & data collection	