Dr. Veena Joshi, Dr. Kaveri Gavade, Compensation to Clinical Trial Participants

Introduction: Clinical Trial (CT) compensation guidelines are available in some countries in Europe, Newzeland and USA. In India, there has been lack of availability of such guidelines to be used by pharmaceutical companies and clinical research organizations (CRO). The issue of compensation to research participants for injury caused while participating in the trial has only been addressed by few researchers. The objective of this study is to understand Principal Investigators' (PI) and Institutional Ethics committee members' (IEC) perspectives on compensation to trial subjects.

Method: Anonymous survey was conducted with 25 PIs and with eight Institutional Ethics committee (IEC) members. A questionnaire was designed to understand PI's views on Clinical Trial (CT) compensation guidelines, variation and complexity in subject compensation related issues and procedures. IEC members were asked questions to appreciate their viewpoint on clear guidelines, uniform format and procedures related to compensation to trial subjects, whether fair compensation is offered to trial subjects in terms of medical care, allowance, insurance etc. and their suggestions on compensation related matters.

Results: Response rate for PIs was 68% and for IEC members was 100%. 53% of the PIs are aware of CT compensation guidelines. When asked which guidelines you use, only two PIs answered: ABPI and Schedule Y guidelines. All PIs and IEC members agreed that guidelines on compensation for patients participating in CTs lack uniform format and procedures. All PIs agreed that compensation should be paid in the event of death, damage or lasting disability being produced by a product involved in the study. IEC members suggested that compensation should be given throughout the life span to the subjects in case of irreparable injury due to trial, to compensate nominated relative in case of participant's death due to participation in CT, compensation should be paid for time, effort, inconvenience, and loss of wages particularly for phase one participants and insurance document should be clear and explicit.

Conclusion: The results suggest urgent need for crystal clear guidelines to manage the dilemma of compensation to "no fault" injury to subjects who suffer adverse effects as a result of their participation in clinical trials.

Paper presentation at FERCI, Nov 2011 By Dr Veena Joshi-

"Prevalence of Tobacco addiction and role of parents in influencing tobacco addiction among adolescents in Pune"

Kelkar DS , Patwardhan M , Joshi VD, Kaveri Gavade

Background: Researchers have put forward the most consistent finding that adolescents are significantly more likely to smoke if their parents smoke. Parental expectations that their child will avoid smoking have been shown to affect levels of adolescent tobacco use. The objective of this study was to find prevalence of Tobacco Addiction (TA) and assess parental influence on Tobacco Addiction among adolescents in Pune.

Method: A cross sectional study was conducted with 6577 adolescents aged 12 to 20 years from 21 schools & junior colleges in Pune during year 2005/6. Data on socio demographic profile, family members' and respondents' tobacco addiction (TA) was collected by self-administered questionnaire. Statistical tests used were t test, chi square test and logistic regression.

Results: Full data on age, gender, participants' and family members' consumption of tobacco was available for 6091adolescents. This data was used for analysis. Average age of the respondents was 16.1 ±1.79 years. 51% were boys. 9% adolescents were residing in the hostel. 36% of adolescents' family members were tobacco addicted. Among family members who were TA, 81% were fathers, 8.2% were brothers, 3.2% were mothers and the remaining were others. The prevalence of TA was 4.2% (7% among boys and 1.3% among girls). Significantly ($p<.0001$) more adolescents were TA whose family members were TA as compared to adolescents whose parents were not TA (7.3% vs 2.4%). Average expenditure on TA was significantly ($p =.004$) higher among respondents with parents addicted to tobacco as compared to respondents with parents who were not addicted to tobacco (Rs 136/mth vs 122/mth). Univariate analysis (binary variables as adolescents who were TA vs who were not TA) showed that adolescents were likely to be more TA with increasing age (OR = 1.44; $p<.0001$), if adolescent is a boy compared to a girl (OR = 4.1, $p<.0001$), staying in a hostel vs not staying in hostel (OR = 1.6; $p = .014$) and if his/her family members were TA as compared to family members not TA (OR = 3.1; $p<.0001$). Association of family members' TA with adolescent's TA still persisted (OR = 2.6; $p<.0001$) after adjusting for gender, age and staying in the hostel.

Conclusion: This study implies that the future prevention programs should be directed towards parental TA. Upcoming studies should explore if parents discuss tobacco-related issues with their children in a constructive and respectful manner. This may help prevent young people taking up smoking.

Paper presentation at Public Health Research Conference, University Of Pune, Oct 2011
By Dr Veena Joshi

Public awareness of clinical trials: A qualitative pilot study in Pune

Veena Joshi, Aditi A. Kulkarni

Abstract

Context: Medical expertise combined with availability of patients with varied diseases have resulted in rapid increase in number of clinical trials (*CTs*) recruiting millions of patients in India. Yet, few researchers have tried to understand if the *public* in India is *aware* of *CTs*.

Aims: To explore the *awareness, perceptions of and attitude* towards participating in *CTs* among *general public* in Pune. **Materials and Methods**: *Focus group discussions (FGDs)* and interviews were conducted by contacting people in the community of various age groups and socio economic status with 7 *Trial participants (TPs*) and 17 *Non Trial Participants (NTPs*). The survey tool consisted of open-ended questions that assessed the *awareness and attitudes* of the individuals regarding the *CTs*. Interview were recorded on paper and translated from (Marathi) local language to English for analysis. Qualitative analysis was used to report the findings. **Results**: Most participants could associate *CTs* with medicine or development of new medicine; however they did not have a good understanding of the manner and safeguards with which *CTs* are conducted. Participants were not aware about different types of *CTs* and phases of the *CTs*. *CTs* were felt to be of benefit to the community and advancement of science. However, due to fear of adverse effe *cts*, 80% of the respondents were not ready to participate in the *CTs*. **Conclusions**: The Indian Pharmaceutical company is the world's 3rd largest by volume as per Dr. Shivathanu Pillai's report 17th March 2010, in spite of that it has been noticed that the *awareness* about *CTs* is very low; therefore there is a need to create *awareness* about *CTs* which helps the participants to participate in *CTs* based on their own decision. These *FGD* findings require validation in a larger sample.

PICR October –December 2012 Vol 3 Issue 4

Presented as Moderated Discussion in the Conference: Advancing Ethical Research 3 to 6 Dec 2012, San Dieago, USA

Public Awareness of Clinical trials: A Pilot study in central west India

Veena Joshi, Gauri Oak, Aditi Kulkarni, Varada Biwalkar

Background: Over 100 companies are currently conducting clinical trials (CTs) in India recruiting millions of participants. But, few researchers have thought about public's awareness of CTs. The objective of this study was to explore public awareness of CTs and their opinion on various methods to create CT awareness.

Method: Cross sectional survey was conducted (Dec 2011 - Feb 2012) with 200 Non Trial Participants (NTP) and 40 Trial Participants (TP) by contacting friends / relatives of patients who were seeking treatment at outpatient clinics at a tertiary hospital in Pune city. TPs and NTPs had to answer same eight questions on CT awareness.

Results: 200 out of 235 (85%) NTPs and 40 out of 43 (93%) TPs agreed to participate in the study and completed the questionnaire. TPs were significantly ($p < .0001$) older than NTPs (51 ± 15 vs 39 ± 14 years). There were more men TPs than NTPs (60% vs 48%). Care was taken to include NTPs from all socio economic categories. 25% of the NTPs claimed that they were aware of CTs. However, among them, few percent participants did not know that CTs are conducted on animals (20%); CTs are conducted on humans (16%), CTs are conducted for the development of new drugs (6%) and18% thought that CTs are conducted only on terminally ill patients. None of the NTPs were aware of the number of phases conducted in CT and only one participant (1/200) knew about the various different types of trials conducted. Among TPs, 72% participated because they trusted the doctor. 95% confirmed that trial was explained to them; however, 20% of TPs did not know which type of trial they had participated. 96% of all participants felt that CT awareness must be created among general public. Conducting seminars, workshops, talks (96%). imparting results of completed studies, use of print media, including clinical trial related topics in higher secondary syllabus, TV serial on clinical study, putting posters in hospitals and clinics (all 87%) are the best ways to create CT awareness. **Conclusion:** Clinical Trials are not well understood by general public. There is urgent need to create CT awareness in India so that participation can be a conscious decision.

Presented as Moderated Discussion in the Conference: Advancing Ethical Research 3 to 6 Dec 2012, San Dieago, USA

Validity and Reliability of Public Awareness of Clinical Trials questionnaire.

Veena Joshi, Gauri Oak, Aditi Kulkarni, Varada Biwalkar

Background: Thousands of people participate in various Clinical Trials (CTs). We designed a survey questionnaire based on focus group discussions and interviews with non-trial participants (NTPs). The aim of this pilot study was to determine the factor structure, reliability and validity of statements in Public Awareness and Perceptions of Clinical Trials survey questionnaire. Method: After deciding the face and content validity, cross-sectional study gathered data on 200 NTPs, age >/=21 years in Erandavane area of Pune city from December 2011 through February 2012. Fifty participants were re tested within one week. Data was analyzed using an exploratory factor (principal component) analysis [PCA] to obtain the factors. The survey employed 27 statements on knowledge about CT, CT benefits / risks, reasons for participation and awareness of CTs which participants ranked on a five-point Likert scale. We determined construct validity, Cronbach's alpha coefficient to determine internal consistency reliability, test retest reliability, and correlation of the sub-scales with age, occupation and education to determine convergent and divergent validity. Results: Average age of the participants was 39 +/- 14 years. 48% were men. After checking the interclass correlations, four items were removed due to poor item-total correlation. The exploratory factor analysis identified five critical factors (F). Benefits of CT (F1), Risks of participation in CT (F2), Knowledge of participation and consent (F3) and Awareness about CTs (F4 & F5). These factors explained 66.19% of the variance (using PCA), The result was confirmed using Principle axis factoring (PAF). Reliability Cronbach's alpha was .817 for all 23 statements. Test retest reliability was .858. Correlation of items within subscales was higher than correlation of items outside subscales in 90% of the cases. CT participation and. consent formalities subscale significantly (p </=.05) differentiated between those who were aware and those who were not aware about CTs. Knowledge of participation, benefits and risks subscales were found to have significant associations with socio economic status, confirming convergent and divergent validity.Conclusion: This pilot study provided practical, reliable and valid survey instrument to assess public perceptions of clinical trials. The result needs to be confirmed with large, diverse population by applying Confirmatory Factor Analysis.

Title: Validity and Reliability of English and Marathi Oswestry Disability Index (ODI) in Indian population
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Year: 2013

Journal: Spine
EpubDate: 2013/02/06
Date: Feb 1
Alternate Journal: Spine (Phila Pa 1976)
DOI: 10.1097/BRS.0b013e31828a34c3
Accession Number: 23380824
Abstract: ABSTRACT:: Study Design: Survey. Total 200 LBP patients completed English and Marathi ODI questionnaire (100 each), visual analogue scale (VAS) and Roland Morris Disability Questionnaire (RMDQ).Objective: To validate English and Marathi version of ODI.Summary of Background Data: Patient-orientated assessment methods are important in the evaluation of treatment outcome. The Oswestry Disability Index (ODI) is one of the condition-specific questionnaires recommended for use with patients with low back pain (LBP).Methods: An adaptation of the ODI for Marathi language was carried out according to established guidelines.Results: Average age of patients who answered English ODI was 42 +/- 15 while Marathi patients were 52 +/- 15 years. About 40% were men. Cronbach's alfa reliability was 0.877 for English and 0.943 for Marathi. 47 and 53 of these patients were retested with English and Marathi ODI within 2 weeks (to assess test-retest reliability). The interclass correlation coefficient (ICC) for the test-retest reliability of the questionnaire was 0.877 and, 0.943 for English and Marathi respectively. The ODI scores correlated with VAS pain intensity ($r = 0.67$, $P < 0.0001$) and RMDQ score ($r = 0.71$, $P < 0.0001$) for English and VAS ($r = 0.325$, $P < 0.001$) and RMDQ scores ($r = 0.503$, $P < 0.0001$) for Marathi. Receiving Operating Curve analysis showed comparable performance in discriminating the existence of sign and symptoms (AUC = 0.947 $p<.0001$, 95% CI: .893 - .999 for English and Marathi (AUC: 0.834, $p<.0001$, 95% CI: 0.735 - 0.933) for severe compared to non severe LBP proving discriminative validity. Results showed that English ODI is valid and reliable. Conclusion: Marathi version of Oswestry questionnaire is reliable and valid, and shows psychometric characteristics as good as English version. It should represent a valuable tool for use in future patient-orientated outcome studies for population with LBP in India.

Prevalence and Causalities of Tobacco Consumption (TC) among Adolescents: A Cross Sectional Study at Pune

DS Kelkar 1, M Patwardhan 2, VD Joshi 2

Abstract

Background and objectives: Health risks associated with tobacco consumption (TC) are well known. The aim of this study was to assess the prevalence and causality of tobacco consumption among adolescents.

Methods: A cross-sectional study was conducted with 6577 participants aged 12 to 20 years from 21 schools and colleges in Pune during year 2005/6. Data on socio demographic profile, family members' tobacco habits and respondents' tobacco consumption habits were collected by self-administered questionnaire. Convenience sampling method was used for data collection.

Results: Complete information on age, gender and participants' consumption of tobacco was available for 6119 students. This data was used for analysis. Average age of the students was 16.9 ±1.79 years. 51% were boys. 9% lived in the hostels. Prevalence of TC was 4.2% (256). Prevalence increased from 2.1% at <14 years to 9.8% at 18 to 20 years of age. Respondents aged <14 years spent about Rs. 110 per month on tobacco while those over 18 years of age spent about Rs.142 per month ($P<0.05$). Significantly ($p< 0.0001$) more boys (85.2%) consumed tobacco compared to girls (14.8%). Hostel residents consumed tobacco more than those not living in hostel (13% Vs 8.6%). Significantly more ($p<0.0001$) number of fathers and brothers of TCs consumed tobacco than non TCs. (Fathers: 53.1% Vs 29.7%), (Brothers: 5.7% Vs 1.1%).

Conclusion: Tobacco consumption among adolescents in Pune is low. However to reduce it further, intervention should start prior to teenage before they form their opinion and start consuming tobacco