

Compensation for Clinical Trial Participants

Dr. Veena Joshi*, Dr.Kaveri Gavade

(*Assist. Director Research, Deenanath Mangeshkar Hospital & Research Centre, Pune)

Presentation at

Forum for Ethics Review Committee in India (FERCI) National Conference on Research Ethics,
Mumbai.

5th/6th Nov 2011



Study Design

- Background:
 - The Indian pharmaceutical industry is the world's third-largest by volume.¹
 - In India, there have been no guidelines providing for uniform formats and procedures to be used by pharmaceutical companies or Clinical Research Organizations (CRO) to report serious adverse events (SAE) in clinical trials².
 - Experts find gross discrimination in paying compensation to trial participants by MNCs³
- Aim:
 - To understand Principal Investigators' (PI) perspectives on compensation to participants participating in Clinical Trials,
 - Institutional Ethics Committee (IEC) members' views, concerns and suggestions related to compensation to trial participants.
- Method:
 - ✓ Anonymous survey with 25 Principal Investigators (PI) and 8 Ethics committee members
 - ✓ 2 separate Questionnaires used
 - ✓ For PI- 5 point Likert scale with free text plus open ended questions
 - ✓ For EC- members- open ended questions.

1. <<http://www.biospectrumindia.com/content/BSTOP20/10506153.asp>>15 June 2005.; http://pharmexcil.org/data/media_files/media_file_81.pdf, March 2010
2. For better Regulation of Clinical Trials, The Economic Times, 21st July 2011.
3. Pharmabiz.com, 11th Oct 2011.



Results:

Response rate: PIs 76%; IEC members 100%.

Q & A on Compensation Guidelines

1. **Are you aware of any 'Clinical Trial (CT) Compensation Guidelines'? If yes, which guidelines do you use?**

75% of the PIs were aware of CT compensation guidelines.

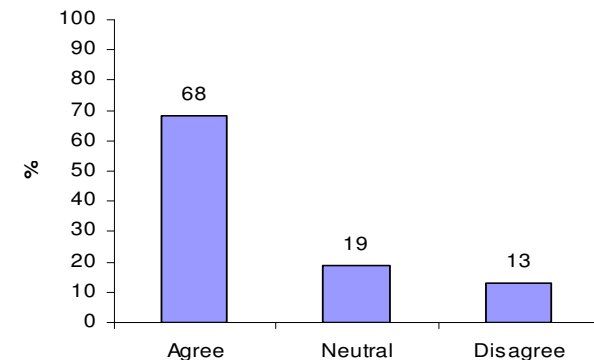
Only one PI has mentioned that he uses ABPI guidelines & another said Schedule Y.

3. **Many times, variety of measures of compensations are being applied by pharmaceutical firms which are often not in the spirit of guidelines.**

missing-1

2. **Guidelines on compensating patient participating in a clinical trial lack uniform formats and procedures.**

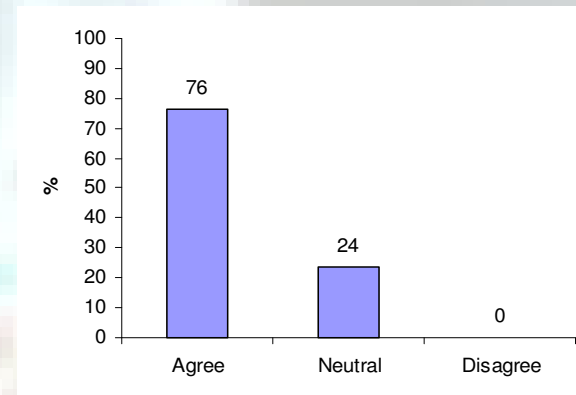
All PIs agreed (1 missing)



Q & A on fair treatment and insurance

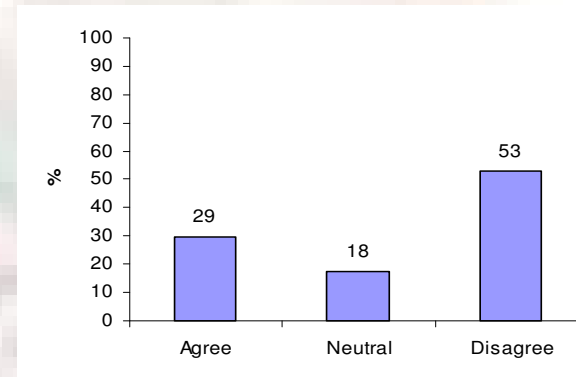
4. **Subjects are assured fair treatment in the event of 'no fault' injury.**

Agree-13, Neutral-4, Disagree 0



5. **Injured subjects should get the reimbursement/compensation only for that part which is not covered in his/her own medical insurance.**

Agree-5, Neutral-3, Disagree-9

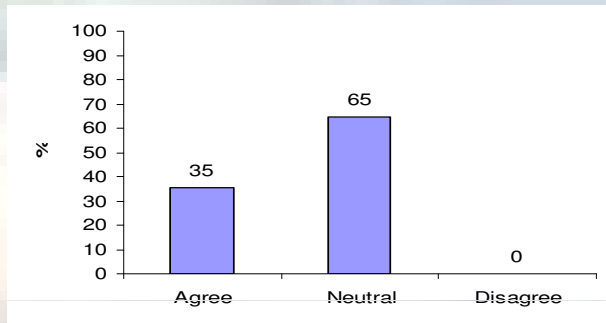


Who should get the compensation?

6. Compensation should be offered for mental impairment and/ or emotional distress.

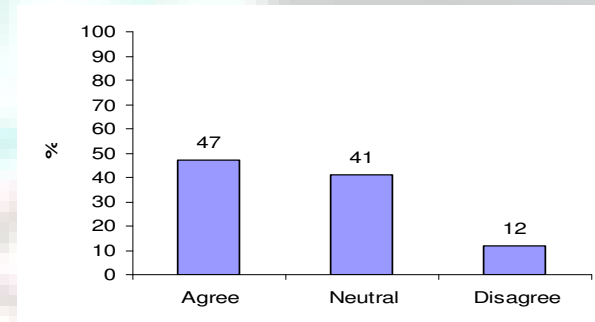
Agree- 6, Neutral-11, Disagree- 0

Ref: ICMR page 5 ,Principal of non exploitation



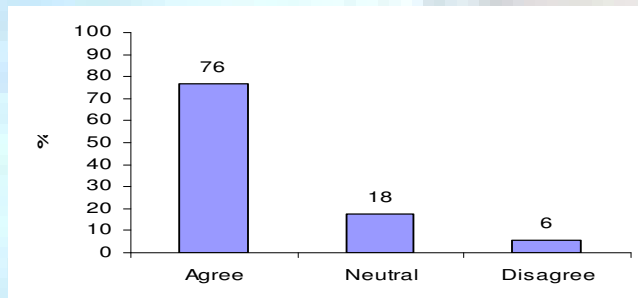
8. Compensation should be paid even if pain is temporary.

Agree- 8, Neutral-7, Disagree-2



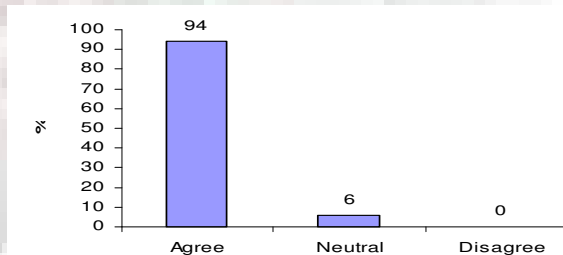
7. Compensation should be paid for adverse reaction causing the injury which was foreseeable or predictable.

Agree-13 , Neutral-3, Disagree-1



9. Compensation should be paid when the company has been negligent in relation to research or development of medical product under trial.

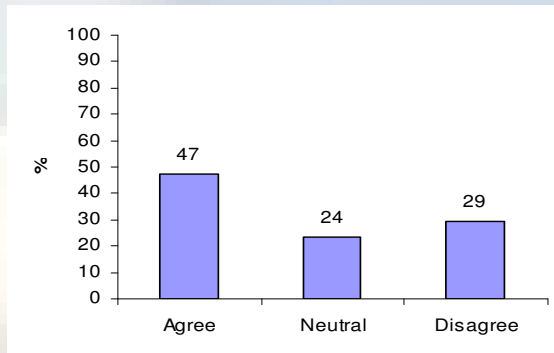
Agree-16 , Neutral-1, Disagree-0



When should compensation be paid?

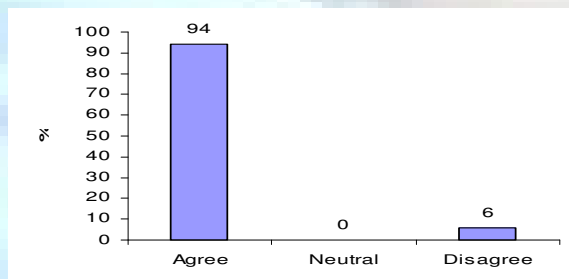
11. Compensation should be paid for patients who are receiving placebo.

Agree-8 , Neutral-4, Disagree-5



12. Compensation should be paid even if the SAE occurred is due to the control drug.

Agree-16 , Neutral- 0, Disagree-1

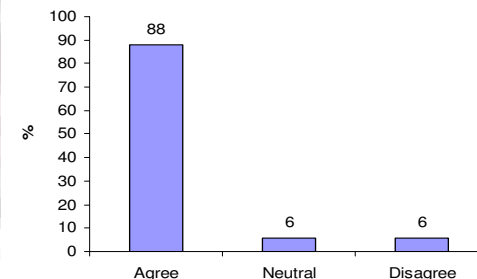


13. Compensation should be paid in the event of death, damage or lasting disability being produced by a product involved in the study.

Agree-16 , Neutral- 0, Disagree-0, Missing-1

14. The amount of any compensation should be appropriate to the nature, severity & persistence of any injury which was caused by drug used in clinical trial.

Agree- 15, Neutral-1, Disagree-1



Disbursement of Compensation

- **Have you ever faced any difficulty while compensating the subject injured due to study related injury? PI. put a tick if you agree.**
 - ✓ Sponsor took a lot of time to send the amount.
 - ✓ Sponsor did not reimburse, instead, I had to pay the entire amount.
 - ✓ Subject was not satisfied with amount of the compensation given.
 - ✓ Looking at subject's condition, I was not sure how much compensation should be given.
 - ✓ Subject complained to me for the time and efforts he took to receive the reimbursement.
- **Once the investigator confirms that the injury is related to IP, how long it takes to decide on the compensation that should be offered?**
- **Once the amount of compensation is finalized for a research related injury, how long it takes subject to actually receive it?**
- **If subject refuses any allowance, what do you do?**
- **Media is creating awareness about 'compensation given to the trial subjects. Please comment.**

Only two PIs stated that Sponsor took long time to send the amount, another PI had to pay once from his pocket..



IEC members' Concerns about Informed Consent Document (ICD)

ICD does not mention Compensation will be given for trial injured subjects

- If subject is on Placebo,
- In case of any temporary or permanent impairment or disability,
- In case of death (to the nominee),
- In case of any psychological / mental injury,
- Post trial access if the drug is effective,
- wage loss, time, effort and inconvenience especially for phase I participants,
- Time frame within which the subject should receive compensation,
- Specific travel allowance and when will the subject receive it
- Full Insurance coverage for research related injury, what is the coverage for, availability immediately after the injury.

&

ICD should state that the Subject has a right to claim compensation in case of research related injury & whom to contact



IEC members' suggestions

- Third party check to make sure that the injury is IP related.
- There should be provision for the subject to get legal/DCGI protection.
- Liability of the company and it's responsibility towards patient should be spelled out in Clinical Trial Agreement.
- Patient Information Sheet & ICD document should be clear, explicit, providing detail information about compensation and it should be in simple language that is easy to understand.
- Submit insurance policy for IEC review.
- Dedicated legal expert with medical qualification should be available to review insurance and other legal documents.





Food for thought

- **Is there any scope for more specificity in guidelines for Ethics Committee?**
- **What should be the allowed limit for Ethics committee intervention in assessing whether the subject's safety and well being is protected and whether the Informed consent process is carried out properly?**
- **Is there any scope to come to a uniform wording regarding compensation in the Patient Information Sheet & ICD?**



Summary and Conclusion

- The results suggest **urgent need for crystal clear guidelines** for sponsor, PI and Ethics committee members to manage the dilemma of “no fault” injury for participants who suffer adverse effects as a result of their participation in clinical trials.
- **Transparent** and explicit mechanism is required to overcome ambiguity and inconsistency to report SAEs and offer Compensation for protection of trial subjects.
- **Compensation** to trial injured participants by the sponsor should be **legally mandatory**.
- Need to create awareness about compensation at all levels- trial subjects, PI, IEC .
- The guidelines on compensation to trial victims to be provided by The Drugs Control general of India (DCGI) would be in consultation with all the stakeholders⁴.

Ref 4: Pharmabiz News – October 14, 2011, 0800 IST



Patient's rights

PI's responsibility

•Compensation

Thank You

Company liability

Sponsor's responsibility

insurance

Injury related to IP

SAE

