Review Article

Compensation for clinical trial participants in India: A regulatory overview

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ABSTRACT

Clinical research is the branch of health-care science which deals with safety and efficacy of medications, devices, diagnostic test, and treatment regimen in human. Good clinical practice (GCP) is an ethical and scientific quality standard for designing, conducting and recording trials that involve the participation of human subjects. An expert committee set up by Central Drugs Standard Control Organization (CDSCO) in consultation with a clinical expert has formulated this GCP guideline for generation of clinical data on drugs. The drug technical advisory board, the highest technical body under D and C, act, has endorsed adoption of this GCP guideline for streamlining the clinical studies in India. The new drug regulatory processes come under the drug controller general of India who is head of CDSCO. ScheduleY has three major section and 11 appendices that are an application for permission, clinical trial, and studies in special population compensation in clinical trials which means participants receive monetary or other benefits for their participation (suffer and harm) in the clinical trial. Compensation is more common in phase 1 trials with healthy volunteers and is usually paid to participants. Some cases compensation is not paid to participants depend on the sponsor and the study design. Many clinical research organizations even advertise participation in clinical studies as it offers a (limited) possibility to earn money. Compensation is always a special concern with vulnerable populations, particularly in children and people with intellectual or mental disabilities. People in these vulnerable populations do not or cannot make their own decisions. Compensation amount will vary from a minimum of Rs. 8 lakhs to a maximum of Rs. 73.60 lakhs depending on the age of the deceased and the risk factor.

Keywords: Clinical research, Central Drugs Standard Control Organization, Drug controller general of India, good clinical practice

INTRODUCTION AND OVERVIEW

Clinical trials are a set of test in drug development and medical research that achieve safety and efficacy data for health interventions in human beings according to drug and cosmetic rule *"Clinical trial is efficient study of new drug(s) in human subject(s) to achieve data for detecting and authenticating the clinical, pharmacological (including pharmacodynamics and pharmacokinetic) or adverse effects with the objective of determining safety or efficacy of the new drug."*[3] Meinert (1986) indicated that a clinical trial is a research activity that involves the administration of a test treatment to some experiment unit to evaluate the treatment.[2] Compensation may be defined as any losses, injury, suffer, medical disaster, organ failure, disability or death occurring during the clinical trial then money is awarded, or something that counters balance or makes up for an undesirable or unwelcome state of affair patient.[3] If any subject or volunteer is participating in the clinical trial, then the money or amount paid is known as "Honorium." According to report published on May 20, 2017, the drug controller general of India (DCGI), G.N. Singh, addressing the annual US-India BioPharma and Healthcare Summit in Boston, announced that the government of India is set to launch a new clinical

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trial policy that will promise greater transparency and better checks for patient safety. Between 2005 and 2012, about 2868 participated in clinical trials which were conducted by pharmaceutical companies and 2800 patients died. During this peak, it was revealed (in 2009) that 24,000 girls were engaged in the human papillomavirus (HPV) where some subjects experience pain, injury or even death during the trial, an another report published on August 22, 2017. Woman wins$110 million compensation after justifying talc powder induced her terminal ovarian cancer from these incidents, government of India frames the rules and regulation regarding compensation for research participants.[4] Compensation in research is compensated usually for two objectives: First one is for ISFOR participation in clinical trial and second is for trial-related injuries.

HISTORICAL TIMELINES GIVING BIRTH TO COMPENSATION GUIDELINE

The first documented experiment resembling a clinical trial was conducted by King Nebuchadnezzar which is known as "book of Daniel." Nebuchadnezzar ordered his people to eat only meat and drink only wine. However, several young men of royal blood, who preferred to eat a vegetable. The king allowed these rebels to follow a diet of legumes (different types of beans) and water but only for 10 days. At the end of the experiment, the bean-loving people appeared healthy and nourished than the meat-eaters, so the king allowed them to continue their diet.[5] (1932–1972) The Tuskegee Syphilis Study, for 40 years, distressed syphilis-positive African Americans were lied to and misled in the name of science. The United State Public Health Service directed studies on 600 (including 201 control) subjects to study the effects of syphilis. Subjects did not provide informed consent and were antithetical access to Penicillin, a proven analyzing for syphilis. Many died as a result, infected others with the disease, and passed congenital syphilis to their children. 1939–1945 Nazi experiment (World War-II experiment), freezing experiment, twin's experiment and thalidomide tragedy and so on, the experiment's lead to death, trauma, and permanent disability. The first trial to use a design now recognized the gold standard was that of streptomycin in 1948 the trial was reported by the Medical Research Council and announced in the new era of clinical trials. This trial was a randomized one and enlisted 107 patients suffering from pulmonary tuberculosis. It was handled since pulmonary tuberculosis was the most important cause of death, of young adults in Europe and North America and streptomycin had been exposed to have good anti-tubercular action in guinea pigs. In the streptomycin group, four out of 55 patients died while in the bed rest group the death rate was 15 out of 52 patients. If streptomycin was not used the death rate in the control group may have remained unchanged, but it would have gone up in the active group. The 72nd report of the parliamentary standing committee on alleged distortive in the conduct, if the studies using HPV vaccine by a foreign non-governmental organization (NGO) name programmed for devoted technology in health in India were granted to the Rajya Sabha on August 30, 2013. In India, the tribal girls were included in phase four trial of HPV vaccine. There were reports of the death of seven girls in the same trial which led to the suspension of the whole process a year.[4-7] In an outrageous act obligated to apprehension the medical ethics community, as many as 233 mentally-ill patients in Indore were subjected to clinical trials to check the efficacy of various drugs, including 42 patients for dapoxetine, a drug to cure premature ejaculation. In January 2008 and October 2010, the trials were handled at private clinics by doctors of the mental hospital attached to the Mahatma Gandhi Medical College, Indore, this appears to light following Madhya Pradesh CM Shivraj Singh Chouhan's answer to a question raised in the assembly. Significantly, the doctors connected had taken the consent for the trials from independent ethics committees attached to private hospitals within and outside the state, bypassing the Mahatma Gandhi Medical College's own Institutional Ethics Committee. Chouhan's reply, tabled in the gather, mentioned the names of five mental hospital doctors involved in the trials – Ramgulam Rajdan, V S Pal, Ujwal Sardesai, Abhay Paliwal, and Pali Rastogi. It also came to light that the clinics where the trials were controlled did not have the mandatory registration certificate from the district chief medical and health officer. MP's chief medical and health officer, Dr. Sharad Pandit, told TOI that his office had registered a few clinics on the recommendation of the MG Medical College dean. However, two doctors mentioned in the CM's reply claimed they had done no wrong. "We did the trial in private clinics, so we took the approval from independent ethics committees," said Dr. V S Pal. Asked why the MG Medical College's own Institutional Ethics Committee was bypassed, he refused to comment.[4] Green chemistry was established very earlier. It can be linked to flutter activities of environment like Rachel Carlson. She published "Silent Spring," in 1962 which was directly helpful to the public's attention related to pesticides and also their connection to environmental pollution Green chemistry is also noted as sustainable chemistry. It is desired to form of chemical products and procedures that cut down generating of hazardous chemical substances. Green chemistry practices diagonally the life cycle of a chemical product, along with its manufacture, use, design, and ultimately disposal. Green chemistry is very suitable in the prevention of pollution at the molecular level, it gives innovative scientific solutions, and it cut down the negative impacts of chemical products on human and the environment health. Chemists are using their contemporary and creative skills from all over the world to build up new processes, reaction conditions, synthetic methods, catalysts, etc. Profitable applications of green chemistry have led to intellectual research to find out different alternatives to active artificial methods and some environmental laws.[5-10]

In January 2012, a mandate application was filed before the supreme court of India ("the court") by Swasthya Adhikar Manch ("SAM"), a "NGO,"[4] against the Ministry of Health and Family Welfare, Government of India, alleging several flaws in the regulatory framework surrounding clinical trials in India. The mandate application was later joined with an independent process petition filed by Bhopal Gas Peedit Mahila Udyog Sangathan ("BGPMUS"), addition NGO, alleging that flaws in the regulatory framework connected to clinical trials had led to exploitation of the civilian population. The two petitions are now being heard together (the petition filed by SAM and by BGPMUS collectively referred to as the "Petition").

As per the announcement, no new clinical trials will be allowed to be conducted in India for at least 2 months from January 22, 2013 ("effective date").

Table 1:Timeline of clinical trial

S. No	Year	Event
1	605 BC	Book of Daniel
2	500 BC	The hippocratic oath
3	1025 AD	Avicenna: Cannon of medicine
4	1537	Ambroise pare: First clinical trial of a novel therapy
5	1747	James Lind's scurvy experiment
6	1800	Arrival of placebo
7	1887	NIH founded
8	1906	FDA pure food and drug act
9	1928	Sir Alexander Fleming discovers penicillin
10	1932–1972	The Tuskegee syphilis study
11	1937	Elixir sulfanilamide disaster
12	1938	Federal food, drug and cosmetic act A series
13	1939-1945	World War II Experiments
14	1944	Multicenter studies
15	1944–1974	Human radiation experiment
16	1947	Nuremberg code
17	1951	Henrietta lacks
18	1964	Declaration of Helsinki
19	1974	The national research act
20	1974	FDA Bureau of medical devices and diagnostic products
21	1979	The Belmont report
22	1981	FDA regulations Title 21
23	1990	International conference on harmonization guidelines
24	1991	The Common Rule
25	1993	Med watch
26	1996	The World Health Organization guidelines for good clinical practice

NIH: National Institutes of Health[8-12]

Article 21

According to Bhagwati, J., and Article 21 "demonstrate a constitutional expense of supreme concern in a democratic society." Iyer, J., has described Article 21 as "the agenda *Magna Carta* protective of life and liberty."This right has been held to be the heart of the structure, the most organic and progressive plan in our living constitution, the foundation of our laws. Article 21 can only be challenged when a person is disposed of his "life" or "personal liberty" by the "State" as defined in Article 12. Negligence of the right by private individuals is not within the view of Article 21.

Article 21 secures two rights:

1. Right to life
2. Right to personal liberty.

The article impedes the privation of the above rights except according to a method established by law. Article 21 corresponds to the *Magna Carta* of 1215, the Fifth Amendment to the American Constitution, Article 40 (4) of the Constitution of Eire 1937, and Article 31 of the Constitution of Japan, 1946. Article 21 applies to natural persons. The right is available to every person, citizen or alien. Thus, even a foreigner can claim this right. It, however, does not entitle a foreigner the right to reside and settle in India, as mentioned in Article 19 (1) (e). Article 21 of the Constitution of India, 1950 provides that, "no person shall be deprived of his life or personal liberty except according to procedure established by law." "Life" in Article 21 of the Constitution is not merely the physical act of breathing.[18-22]

AUDIO VIDEO RECORDING

The interview schedule was arranged to determine the consent of study subjects with regard to A-V recording of the consent process. The schedule was developed in English, adapted into the local language, and confirm by back translation. The interview was a framework around a given theoretical scenario in which A-V recording of the consenting course was planned. The subject's willingness to participate in the study, if A-V recording of consent progress is to be done, was checked and further, the main reason for not consenting for A-V recording was extracted. Only the subjects with written informed consent were included in the study.[23-25]

COMPENSATION RULE IN INDIA

By overall application of the compensation motto, the drugs and cosmetic rules have been amended wide GSR 53 (E) dated January 30, 2013 inserting a rule 122 DAB in schedule Y the amendment specifies the policy for prepare of report serious adverse event (SAEs) including death occurring during clinical trial to report at the cause of death/injury to the subject and to regulate the quantum of compensation if any to be paid by the sponsor or his representative howsoever have obtained permission from the DCGI in a time bound manner. In case of clinical trial related injury or death, the sponsor or his representative pay the compensation as per the order of the DCG (I) within 30 days of the receipt of such order.

The rule state that is any injury or death developing due to any of the following reason:

a) Adverse effect of the investigational product (s) (IP).
b) Violation of the approved protocol, scientific misconduct, or negligence by the sponsor or his representative or the investigator.
c) Failure of IP to provide the intended therapeutic effect.
d) Use of placebo in a placebo-controlled trial.
e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol.
f) For an injury to a child *in utero* due to the participation of parent in a clinical trial.
g) Any clinical trial procedures involved in the study.[3]

Need of compensation

- In case of trial-related injury.
- In case of physical disability.
- In the case of organ failure or trauma.
- In the case of death.
- To comfort participants from financial sacrifice.
- As a token of thanks of participants contribution to clinical research.
- For achieving the sufficient number of the subject within the required time period.[3]

Regulatory body for framing rule and regulation for compensation in India

- Drug and cosmetic rule (1945) schedule Y.
- Indian Council of medical science.

Table 2: Regulatory development for clinical trial

Sr. No.	Date	Development
1	February 6, 2012	The court hears the Petition for the first time. Time is granted to the Respondents-MoHFW, CDSCO, and others to submit a counter-affidavit
2	March 26, 2012	The court grants extension of time to the respondents to submit the counter-affidavit
3	July 16, 2012	The court grants a further extension of time, to submit counter-affidavit, to the respondents
4	October 8, 2012	The court orders the secretary, MoHFW and/or CDSCO, through DCGI, to provide the following information to the court within 4 weeks of the hearing: The number of experimental "NCEs" approved for clinical trials by the DCGI from January 1, 2005, to June 30, 2012 Whether deaths were suffered by subjects of the clinical trials. If yes, the number of deaths occurred Whether serious side effects were suffered by the subjects of clinical trials. If yes, the number of subjects and the nature of side effects The details of compensation paid to the subjects who suffered side effects or paid to the family of the subjects who died
5	January 3, 2013	The court observes that the information, as directed, is not submitted by the secretary, MoHFW or the CDSCO. Instead, an additional affidavit is filed by the Deputy DCGI providing the requested information. The court notes non-compliance of the Order dated October 8, 2012 and decides to ignore the additional affidavit. It re-directs the secretary, MoHFW or CDSCO through the DCGI as well as the Chief Secretary of all states to file an affidavit providing the requested information within 4 weeks from the date of hearing. It takes note of the statement of the additional solicitor general of India that until further order of the court, clinical trials of new chemical entities will be conducted strictly in accordance with the procedure described in Schedule Y of the drugs and cosmetics rules, 1945[5] under the direct supervision of the secretary, MoHFW. The court directs the case to be listed in 4 weeks. It is noteworthy that this matter case coincided with the publication of the Department-related Parliamentary Standing Committee on Health and Family Welfare's Report on the Functioning of the CDSCO on May 8, 2012, which made scathing remarks on regulatory control over the conduct of clinical trials in India, especially in the case of new drugs. It had, inter alia, found that the approvals to clinical trials had been granted without adhering to the provisions of Schedule Y of the Drugs and Cosmetics Rules, 1945 (the "Rules")

DCGI: Drug controller general of India, MoHFW: Ministry of Health and Family Welfare, NCEs: New Clinical Entities, CDSCO: Central drugs standard control organization

Table 3: Update regarding regulatory development in India

Date	Regulatory developments
January 19, 2011	Draft rules to include provisions pertaining to the registration of "CROs" under the rules and to include a Schedule Y-1 which covered the "requirements and guidelines for registration of CROs." Stakeholder comments were invited for these proposed rules and the Schedule Y-1; however, they continue to be in the draft form as no further action was taken by the authorities and the notification yet remains to be implemented
November 18, 2011	Draft rules to include provisions to award compensation to study subjects, by sponsors of trials, in case of clinical trials related to injury or death and consequences of non-compliance
December 21, 2011	Guidelines for the requirement of chemical and pharmaceutical information including stability study data before approval of clinical trials/ bio-equivalence studies
July 17, 2012	Draft rules which outline the required conditions to be met to issue a permission to conduct clinical trials, thereby amending rule 122 of the rules
July 17, 2012	Draft rules to include provisions for registration of the Ethics Committees with the licensing authority before approving clinical trials, and to include, as part of Schedule Y-1, requirements and guidelines for registration of the Ethics Committee
August 03, 2012	Draft guidelines for determining quantum of compensation
August 16, 2012	DCGI order directing ethics committee to conduct surprise visit and keep vigil to see whether clinical trials are being undertaken as per schedule Y/GCP guidelines
August 16, 2012	DCGI notice drawing out a checklist of essential elements in the informed consent document to be obtained from the study subjects and the format of the said informed consent document
August 28, 2012	DCGI order directing importers and manufacturers of "new drugs" to submit pending periodic safety update reports immediate
December 12, 2012	DCGI order directing sites of sponsors/CROs and ethics committees to remain open for inspection to ensure that subjects of clinical trials are safe and that data generated are scientifically and ethically sound
December 12, 2012	DCGI order directing the ethics committees to mandatorily operate according to GCP guidelines issued by CDSCO Since the announcement does not cover suspension of the existing clinical trials; it appears that such trials will continue to be conducted as per the existing rules. However, the announcement could bring the existing clinical trials under cloud as these developments may raise concerns about the adequacy of existing rules and regulations and the uncertainty on proposed new rules being made applicable to the ongoing trials. As it is, the constant activity at the drugs regulators' end to publish draft amendments to the existing legislation with no certainty on when they will be implemented has raised several concerns in the industry. Streamlining the entire process in a balanced manner (that is, creating a fine balance between the sponsors and the CROs/institutions in India) and bringing further clarity to the existing legislation may, perhaps, lead to better implementation, and adherence to the laws/rules/guidelines while conducting clinical trials

GCP: Good clinical practice, CDSCO: Central Drugs Standard Control Organization, CRO: Contract research organizations, DCGI: Drugs Controller General of India[13-17]

- Ethical guideline 2000–2006.
- Indian Good Clinical Practice 2001.
- National Pharmacovigilance program.
- Bioavailability and bioequivalence studies guideline 2005.
- Amendment of drug and cosmetic act contract research organizations registration.
- Central drug standard control organization DCGI.
- Organization for Economic Co-operation and Development.
- These committees after consideration prepared formula to be followed for the determination of the quantum of compensation in case of clinical trial related death.
- The drugs and cosmetics rules have been amended vide GSR 53(E) dated January 30, 2013 inserting a Rule 122DAB in Schedule "Y." The amendment specifies the procedure for processing of reports of SAEs including deaths occurring during clinical trial to arrive at the cause of death/injury to

the subject and to determine the quantum of compensation, if any, to be paid by the sponsor or his representative, whosoever have obtained permission from the DCGI in a time bound manner.

Quantum of compensation in case of SAE (death) related to clinical trial

Three most important factors are age factor, risk factor, and the base amount. Compensation in case of death related to a clinical trial:

$$\text{Compensation} = B \times F \times R/99.37$$

Where,

B= Base amount (8 lakhs).

F= Age factor with varies from 228.54 (<16 years) to 99.37 (>65 years).

R= Risk Factor depending on the seriousness and severity of the disease – scale of 0.5–4.

The compensation amount will vary from a minimum of Rs. 4 lakhs to a maximum of Rs. 73.60 lakhs depending on the age of the deceased and the risk factor. In the case of patients whose expected, mortality is 90% or more within 30 days, a fixed amount of Indian Rs. 2 lakhs should be given.

The committee finally decided to a base amount that is more logical and which remains contemporary/dynamics. It is such that if the nominee of the subject keeps that amount of compensation in the bank by way of fixed deposit, he or she will get and, monthly interest amount which is at least approximately equivalent to minimum wages (reference minimum wages of Delhi) of the unskilled workers. It was considered that the minimum wages as on date (when the formula was finalized) were Rs.7.722/- per month and accordingly base amount (rounded) of Rs. 8 lakhs was considered to be appropriate.

Risk factor

In case of patient whose expected mortality is 90% or more within 30 days, a fixed amount of Rs. 2 lakhs may be given.

- 0.50 – terminally ill patient (expected survival not >6 months).
- 1.0 – Patient with high risk (expected survival between 6 and 24 months).
- 2.0 – Patient with moderate risk.
- 3.0 – Patient with mild risk.
- 4.0 – Healthy volunteers 0or subject of no risk.[3,26]

FACTOR (F) CALCULATING THE AMOUNT OF COMPENSATION ACCORDING TO WORKMEN COMPENSATION ACT

The factor which is based on the age of participants has been derived from the workmen compensation act, which prescribed the factor which based on age for calculation of the lump sum amount of compensation to be paid by the employer in case of permanent disablement and depending on of injured.[3,26]

Table 4: Factor (F) for calculating the amount of compensation according to workmen compensation act

Age	Factor
NMT	
16	228.54
17	227.49
18	226.38
19	225.22
20	224
21	222.71
22	221.37
23	219.95
24	218.47
25	216.91
26	215.28
27	213.57
28	211.79
29	209.92
30	207.98
31	205.95
32	203.85
33	201.66
34	199.40
35	197.06
36	194.64
37	192.14
38	189.56
39	186.90
40	184.17
41	181.37
42	178.49
43	175.54
44	172.52
45	169.44
46	166.29
47	163.07
48	159.80
49	156.47
50	153.09
51	149.67
52	146.20
53	142.68
54	139.13
55	135.56
56	131.95
57	128.33
58	124.70
59	121.05
60	117.41
61	113.77
62	110.14
63	106.52
64	102.93
>65	99.37

NMT: Not more than

The members of the independent expert committee discussed the various possible factors that could be considered while deciding the quantum of compensation. The following factors emerged (Listed below are not on the basis of priority).[4]

Table 5: Factor that could be considered while deciding the quantum of compensation

F1	Age of the subject
F2	Risk of death
F3	Income of the subject
F4	Comorbidity of the subject at the time of SAE (death)
F5	Expected survival
F6	Dependency on the decreased
F7	Concomitant medication
F8	Gender of the subject
F9	Negligence during the conduct of a clinical trial
F10	Duration of the disease
F11	Industry versus academia versus institute versus sponsor
F12	Expectedness of the drug to cause death

SAE: Serious adverse event

The committee met and considered the matter in detail on April 4, 2014. The committee discussed various criteria that could be considered for determination of the quantum of compensation in case of clinical trial related injury, death and injury other than death. In case of death of the subject since the loss of life is the maximum injury possible.

Considering the definition of SAE, the following sequences other than death are possible in a clinical trial subject, in which the subject shall be entitled to compensation in case the SAE is related to the clinical trial.[27-30]

(i) A permanent disability.
(ii) Congenital anomaly or birth defect.
(iii) Chronic life-threatening disease.
(iv) Reversible SAE in case it is resolved.

SAE causing permanent disability to the subject

In case of SAE causing permanent disability to the subject, the committee deliberated that so far as the quantum of compensation is concerned, 100% permanent disability to a subject may not be considered equivalent to the death of the subject. Therefore, even in case of 100% permanent disability, the quantum of compensation should be less than that for the death of the subject. After detailed deliberation, the committee arrived at a decision that quantum of compensation in case of 100% disability should be 80% of the compensation which would have been due for payment to the nominee(s) in case of death of the subject. The quantum for <100% disability will be proportional to the actual percentage disability the subject has suffered.

Accordingly, the committee arrived at the following formula:

Compensation = (D × 80 × C)/(100 × 100)

Where,

D=Percentage disability the subject has suffered.

C=Quantum of compensation which would have been due for payment to the subject's nominee(s) in case of death of the subject.[13,30,31]

SAE causing congenital anomaly or birth defect

The committee opined that the congenital anomaly or birth defect in a baby may occur due to the participation of any one or both the parent in a clinical trial. Following situations may arise due to congenital anomaly or birth defect: (a) Still birth, (b) early death due to anomaly, (c) no death but deformity which can be fully corrected through appropriate intervention, and (d) permanent disability (mental or physical).

Compensation = (D × 80 × C)/(100 × 100)

The committee opined that the compensation in such that if that amount is kept by way of fixed deposit or alike, it should bring a monthly interest amount which is approximately equivalent to half of the minimum wage of the unskilled worker (in Delhi). The committee noted that this aspect was duly considered while fixing Rs. 8 lakhs as the base amount for determining the amount of compensation in case of SAE resulting into death. Hence, the committee decided that quantum of compensation in such cases of SAE should be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to (c) and (d) above to any child, the medical management as long as required should be provided by the sponsor or his representative which will be over and above the financial compensation.[31,32]

SAE causing life-threatening disease

The committee deliberated that the quantum of compensation in such cases should be linked to the duration (in days) for which the subject remained under the life-threatening situation and required medical care, irrespective of number of days of hospitalization. The committee also considered that compensation per day in such cases should be equal to the minimum wage of unskilled worker (of Delhi).

Accordingly, the committee arrived at the following formula.

Compensation=N × W.

Where,

N=Number of days for which the trial subject remained under life-threatening situation requiring medical care, irrespective of number of days of hospitalization.

W=Minimum wage per day of the unskilled worker (in Delhi).[27,31,33]

Reversible in case of SAE it is resolved

In the case of clinical trial related SAE which was reversible and resolved, the quantum of compensation should be linked to the number of days of hospitalization of the subject. The compensation per day of hospitalization should be equal to the wage loss. The wage loss per day should be calculated based on the minimum wage of the unskilled worker (in Delhi).

Since in case of hospitalization of any patient not only the patient loses his/her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant. The committee decided that the compensation per day of hospitalization in such case should be double the minimum wage.

Accordingly, the committee arrived at the following formula.

Compensation = 2 x N x W

Where,

W=Minimum wage per day of the unskilled worker (in Delhi).

N=Number of days of hospitalization.

The committee felt it necessary that the formulas suggested above should be considered as a draft which should be available to the stakeholders for at least 15 days for their suggestions. The formula can be finalized after taking into consideration the suggestions of stakeholders.[30-34]

CONCLUSION

There is a compulsory need for cleared and systemic guideline related to the compensation in a clinical trial. There are many formulae given by Central Drugs Standard Control Organization for calculating the quantum of compensation if any subject suffers, injured, SAE and death occur during the clinical phase he/she awarding with compensation. However, poverty, illiteracy, and ignorance of their fundamental right make them easy for the clinical trial new drug. Participant must know about the trial in his/her language so that they understand. Awareness about the clinical trial participants is also important so that they understand the risk involved in a clinical trial.[3,32,34]

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