Indian Council of Medical Research

Ministry of Health & Family Welfare
Department of Health Research

Minutes of the 2nd Inter-Ministerial / Inter-Agency Meeting to Discuss the Strategy to Regulate the Rampant Practices of Banking and Use of Stem Cells for Therapeutic Purposes

At

ICMR Hqrs, New Delhi on 5th September, 2016 at 2:30 PM

Members:

Dr. Soumya Swaminathan, Secretary DHR and DG, ICMR **Chairperson**
Dr. G.N. Singh, DCGI, CDSCO
Dr. Anil Kumar, DG, RHS
Dr. K.K. Agarwal, General Secretary and President Elect, IMA
Dr. V.G. Somani, Joint DCGI, CDSCO
Dr. A. Ramkishan, DDC, CDSCO
Mr. Shiv Kumar, ADC, CDSCO

ICMR Secretariat
Dr. Vijay Kumar, Scientist G and Head, Division of BMS
Dr. Geeta Jotwani, Scientist E

President MCI, DGHS and Secretary, Health MoHFW could not attend due to prior commitments.

Welcome and Introductory Session

The meeting started with a warm welcome by Dr. Soumya Swaminathan, Secretary, DHR & Director General, ICMR to all members. She apprised the members regarding the alarming commercialisation of unproven treatments using stem cells and cell based products. A strategy to curb such practices was stressed upon. It was further informed that, based on the recommendation of the 1st meeting, the present meeting was being organised to have one –to-one dialogue with the concerned agencies so as to take urgent steps to stop the indiscriminate transplantation of stem cells.

With these remarks, Dr. Swaminathan invited Dr. Geeta Jotwani to present the overview of the issues and concerns in the field. The presentation showcased the screen shots of the websites of various clinics/ hospitals/ stem cell banks openly advertising and luring patient into unproven stem cell therapies. The plights of the patients who had availed such treatments but failed to see any improvement was also displayed through their blogs which highlighted the exploitation of patients. The possible solutions for the concerns and issues were also presented. The agenda of the meeting was discussed item wise and discussion is summarised below.

Discussion:

1. The role of MCI in prevention of abuse of stem cells and promotion of ethical clinical research was discussed. It was informed that despite several invitations, MCI President or its representative fail to attend the meeting making it difficult to strategies the actions that can be taken against erring clinicians. Dr. Agarwal thoughtfully took upon himself that the task of requesting the MCI to nominate a member to be present in future meetings.
2. Dr. Singh stressed upon clear definitions of all the terms including stem cells, stem cell research, therapy, products, academic trial vs regulatory trial, trial requirements etc. which can then be incorporated into the proposed new bill on Drug and Cosmetic Act. This will help to completely demarcate the areas that fall under the purview of ICMR and CDSCO. Moreover as the definitions will be framed by the expert groups in the field, the government agencies will not be questioned on the legitimacy of incorporating them in the proposed bill. Dr. Agarwal opined to include MCI recognised medical colleges amongst those institutions that can do academic trials.
3. Dr. Agarwal proposed to create a white paper on the prevalent practices in the field that can be jointly prepared by ICMR and IMA in view of the Hon'ble Supreme Court's ruling on prevalent practices in medicine.
4. It was also suggested to create a mapping network of all those involved in stem cell transplant. In addition, registry of all stem cell transplants was also proposed in order to monitor the clinical use of stem cells across the country.
5. Creating awareness amongst all the stakeholders and especially the general public was considered as important aspect by Dr. Swaminatahn. It was suggested to write articles in press and e-media for lay man. For making clinicians aware on the rightful use of innovative technologies and the relevant government policies, Dr. Swaminnathan further suggested creating awareness modules and using the IMA webcast platform which has an outreach to almost 5,000 doctors per session, to further the cause.
6. The procedure to file complaint against the doctors offering unproven stem cell therapies was discussed. Dr. Agarwal informed that only written complaints, and not emails are accepted and they have to be filed with the state MCI. He also recommended copying the complaints to the IMA grievance cell. He stated that self regulation in the medical practices is IMA's mandate and necessary action will be taken by IMA in coordination with MCI.
7. Regarding banking of tissues other than umbilical cord blood (UCB), Dr. Somani referred to the National Guidelines for Stem Cell Research -2013 and stated that the various tissues as sources of stem cells other than UCB have been mentioned in these guidelines. Thus banking of these tissues other than UCB cannot be prevented. The matter of several cord blood banks operating without the license of the CDSCO, as indicated from the website of these banks on the internet, was also discussed.
8. The harmonization of all the existing guidelines, rules and acts were discussed. It was informed that a new bill on Drug and Cosmetic Act is being drafted and the suggestions/ recommendations made in the meeting can be incorporated in the proposed document.

Based on the discussions above, following recommendations were made:

Recommendations:

1. **a. Prevention of abuse of stem cells and promotion of ethical clinical research**

   i. To clearly define stem cells; their sources (embryonic, foetal, autologous, allogeneic); use (autologous, allogenic, homologous, non homologous); product definition (time, processing, labelling); approval pathway for each (academic vs regulatory trials); requirements (GMP, GLP, GCP, manpower and appropriate qualification for professionals involved)
   Responsibility: CDSCO in consultation with ICMR

   ii. These definitions will be incorporated into the new bill
   Responsibility: CDSCO

   iii. Till the new proposed bill comes into effect, a gazette notification on the clinical use of stem cell and cell based products can be issued
   Responsibility: CDSCO in consultation with ICMR and IMA

   iv. Creation a white paper on the prevalent practices in the field of stem cell
   Responsibility: ICMR and IMA

   v. Create registry of stem cell and cell based products transplant done by all clinicians across the country
   Responsibility: CDSCO in consultation with ICMR

   vi. To map all the operators in stem cell and cell based products including clinics/ hospitals/ doctor/ institutions by inviting following information in the following format:

Name of the Institution	
Complete postal address	
Email ids	
Contact Numbers	
Source of cells and its use (homologous or non-homologous)	Autologous (marrow/ cord blood/ adipose tissue/ iPSC/ any other tissue – specify) Allogenic (marrow/ cord blood/ adipose tissue/ embryonic/ cadaver/ any other tissue- specify)
Type of cells and level of manipulation	HSC/ MSC/ ESC/ iPSC/ *ex vivo* expansion >48hrs/differentiated (in case of differentiated cells, specify the initial cells and the differentiated cells)
Purpose with specific details	Basic Research Clinical trials Therapy/Transplantation using Stem Cell and other cell based products
Charges levied on patients	

   After the compilation within specified period of 90 days, the list of known operators will be published on website of ICMR, DCGI, IMA with a statement

that "those who are not informed their activities to the Govt., are the operators which are not known to the Govt. and public shall be careful about while taking any treatment

Responsibility: CDSCO in consultation with ICMR

vii. To file complaint or representation against doctors offering unproven stem cell treatments, the patients/ concerned persons can submit a written complaint to state MCI copying the same to IMA grievance cell, CDSCO and ICMR.

Responsibility: the state MCI will initiate action against the erring clinicians

viii. Create awareness amongst all stakeholders regarding the current status of clinical use of stem cells and cell based products and the directions on filing complaints through

a. news article in press and e-media for lay man
b. FAQs that can be put on all relevant government websites for lay man as well as researchers and clinicians
c. Webinars on rightful and ethical use of innovative technologies in the field of medicines for the clinicians using various platforms including the IMA's Medinews and webcast.
d. IMA can specifically inform all its members regarding the unproven stem cell treatment and that no doctors shall offer it.

Responsibility: ICMR, CDSCO and IMA

b. Path and Process to Review Retrospective clinical Data for considering claims for possible therapeutic use

i. The committee unanimously accepted that the proposal inviting 'Letter of Claim' by ICMR and its evaluation by subject expert committee that shall also have members from ICMR, CDSCO, DGHS, IMA, NAC-SCRT.
ii. If found substantial, the claimant/s will have to submit protocol to CBBTDEC for a multi-centric clinical trial
iii. Based on the results, the DGHS will declare the therapy 'as proven' and create standards/guidelines for the same.

Responsibility: ICMR, CDSCO and DGHS

2. Regulations for Stem Cell Banking

i. There is no evidence that stem cells from various sources/tissues other than UCB have definite clinical application as yet. Thus luring clients/ parents with the claims that the stem cells from such sources/ tissues shall be useful in future to treat some disease is an unproven activity.

ii. Subject experts particularly haematologists need to provide list of proven indications of HSCT and same need to be placed on websites of ICMR, CDSCO, DGHS, IMA and MCI including state agencies for information of the general public.

Responsibility: ICMR

iii. Charging for the storage of tissues as source of stem cells other than UCB is not permitted. A statement to this effect to be displayed on the websites of all the all the relevant government agencies/ society/ associations
Responsibility: CDSCO in consultation with ICMR and all the relevant government agencies/ society/ associations

iv. The section on banking in the NGSCR needs to be revised accordingly.
Responsibility: ICMR

v. It was agreed that CDSCO will take appropriate action on the banks functioning in India without license from the licensing authority. All such banks shall inform the clients about the illegal storage and be compensated by the banks appropriately. The UCB stored in such banks can be donated to public banks, if the tissue and documentations for it are found to be satisfactory. ICMR to provide the list of all such banks that are advertising UCB banking in India on internet but do not have a license to do so as their names do not feature in the list of licensed cord blood banks available on the CDSCO website (http://www.cdsco.nic.in/writereaddata/Umbilical-Cord-Blood-Banks-India.pdf).
Responsibility: CDSCO

3. Harmonization of Existing Guidelines and Regulatory Requirements

i. In view of the revision/ drafting of new bill on Drug and Cosmetic Act the lacunae in the existing guidelines and regulatory documents may be further discussed and appropriate definitions to be drafted so as to incorporate into the DCA

ii. While reframing the new bill on Drug and Cosmetic Act, revised draft of NGSCR (2016) may be taken into consideration for harmonization and proper implementation.

Responsibility: CDSCO in consultation with ICMR

The meeting ended with the Chair thanking all the members for their time and inputs.
