

3 Citation of SMA Honorary Member
5 Can Healthcare be Cheap & Good?
6 SARS @ TTSH
7 Heart of a Volunteer
8 Cold Chains & Hot Spots

A Legislative Framework for Stem Cell Research in Singapore

By Dr Balaji Sadasivan, Minister of State for Health and Transport

Editorial Note:

The following speech was delivered by Dr Balaji Sadasivan, Minister of State for Health and Transport, who was the Guest-of-Honour at the SMA Annual Dinner, on 16 November 2003, at the Raffles Town Club.

I am very happy to be here this evening to attend SMA's Annual Dinner. Many of you have distinguished yourselves and excelled in the different fields of medicine. The rapid advances in biomedical research are likely to have an impact on the way we practise in the years ahead.

STEM CELL RESEARCH

One of the most exciting areas of research is in stem cells. The biology of mouse stem cells has been studied in detail for many years. This led to the development of techniques to isolate stem cells from human embryos and the ability to grow these cells in the laboratory. This breakthrough has made the vision of regenerative or reparative medicine a distinct possibility in the near future.

Embryonic stem cells have two important characteristics. The first one is that it is possible for these cells to replicate indefinitely through cell division in their unspecialised state. The second is that under certain physiologic or experimental conditions, they can be induced to differentiate into a wide range of cells including neurons, hepatocytes or muscle cells. The ability of embryonic stem cells to replicate and specialise exceeds that of embryonic germ cells and adult stem cells.

Human embryonic stem cells have the ability to proliferate for a year or more in the laboratory without differentiating. A starting population of about 30 embryonic stem cells in the laboratory can yield millions of cells after a few months of proliferation. The specific factors and conditions that allow stem cells to remain unspecialised are, therefore, of great interest to scientists as it is important to understand the signals in a mature organism that cause a stem cell population to proliferate and remain unspecialised until the cells are needed for repair of a specific tissue.



Dr Balaji Sadasivan, Minister of State for Health & Transport, delivers his speech on stem cell research in Singapore.

Scientists are just beginning to understand the internal and external cellular signals that trigger differentiation. The internal signals are controlled by a cell's genes, which are interspersed across long strands of DNA, carrying coded instructions for all cell functions and structure. The external signals for cell differentiation include chemical secretions by other cells, contact with neighbouring cells and certain molecules in the micro-environment.

There are still a number of critical questions which remain unanswered. For example, are the internal and external signals for cell differentiation similar for all stem cells? Are there specific signals that promote differentiation? Answers to these questions may allow scientists to find new ways of controlling stem cell differentiation in the laboratory, thereby growing cells or tissues that can be used as potential treatments for many degenerative diseases which are currently incurable. This potential has been recognised by scientists and the medical community as a basis for cell-based therapies and also for screening new drugs and toxins and understanding birth defects.

In parallel with these exciting biomedical research findings, there has been much concern over the ethical



EDITORIAL BOARD

Editor

Dr Wong Tien Yin

Deputy Editors

Dr Daniel Fung

Dr Toh Han Chong

Members

Dr Chan Kah Poon

Prof Chee Yam Cheng

Dr John Chiam

Dr Jon Goh

Dr Terence Lim

Dr Oh Jen Jen

Dr Tan Poh Kiang

Ex-Officio

Dr Lee Pheng Soon

Dr Tham Tat Yeon

Executive Secretary

Ms Chua Gek Eng

Editorial Manager

Ms Krysanja Tan

The views and opinions expressed in all the articles are those of the authors. These are not the views of the Editorial Board nor the SMA Council unless specifically stated so in writing. The contents of the Newsletter are not to be printed in whole or in part without prior written approval of the Editor.

Published by the Singapore Medical Association, Level 2, Alumni Medical Centre, 2 College Road, Singapore 169850. Tel: 6223-1264 Fax: 6224-7827 Email: news@sma.org.sg URL: <http://www.sma.org.sg>

◀ Page 1 – A Legislative Framework for Stem Cell Research in Singapore

and social aspects of research carried on human embryonic stem cells, both locally and internationally. To address this concern, the Bioethics Advisory Committee (BAC) was appointed by the Cabinet in December 2000 to examine the ethical, legal and social issues arising from biomedical research and development in Singapore and to make recommendations based on their findings. The BAC examined and deliberated on many scientific, ethical, legal and social issues in this area. It also undertook a very extensive public consultation to understand the concerns and sentiments of local interest groups and the views of the general public. The recommendations of the BAC on ethical, legal and social issues of stem cell research and cloning were submitted to and approved by the Cabinet.

LEGISLATIVE FRAMEWORK FOR GOVERNANCE OF BIOMEDICAL RESEARCH

Based on these approved recommendations, the Ministry of Health (MOH) has been tasked to establish a comprehensive legislative framework and to formulate guidelines for the licensing, control and monitoring of all human stem cell and cloning research conducted in Singapore. This is to ensure that all such research work carried out in Singapore is ethically sound and carefully monitored.

MOH has prepared a draft Bill to give effect to these recommendations. The draft Bill has now been posted on the MOH website for further public consultation from 10 to 30 November 2003.

PROHIBITION OF REPRODUCTIVE CLONING

The proposed Bill will prohibit reproductive cloning. The Bill also requires researchers to obtain prior approval from the Ministry before they can conduct human embryonic stem cell research. The Ministry will examine each research protocol as well as the qualifications of the researchers. Approval would only be given to studies that are of scientific merit and are ethically sound.

LICENSING REQUIREMENTS

This Bill covers biomedical research involving human embryonic stem cells, somatic cell nuclear transfer involving human tissue and research on human tissues. The Bill

requires that such research can only be carried out in institutions approved and licensed by the Ministry.

Each licensed research institution is required to establish and implement transparent and appropriate systems and standards for proper approval, monitoring, supervision and review of these forms of biomedical research.

INSTITUTIONAL REVIEW BOARDS (IRBS)

Each institution is also required to appoint an Institutional Review Board (IRB). The IRB is responsible for reviewing proposed protocols in the defined areas of research to consider the risks, scientific merits and potential benefits, and to ensure that the research is ethically sound before granting its approval. The IRB is also empowered to require modifications to the purpose and methods of research or to disallow conduct of research.

ACQUISITION AND DONATION OF HUMAN TISSUE FOR BIOMEDICAL RESEARCH

A key provision in the draft bill is the requirement to obtain appropriate consent from subjects before they can donate tissues for research or participate in biomedical research projects.

There may have been collections of human tissues that have been obtained before the new Act comes into force. Some of these were originally taken for diagnostic or therapeutic reasons and consent from patients for the tissues to be used for research may not have been obtained previously. These legacy tissues are of great value for biomedical research. In line with the recommendations of the BAC, the Bill will require researchers seeking to use legacy tissues to obtain the prior approval of the IRBs.

This Bill has also established safeguards against the sale and supply of human tissue for the purpose of biomedical research.

CONCLUSION

This legislative framework for licensing, control and monitoring of biomedical research activities would ensure that research work is done ethically. This would strengthen our international reputation and standing as a research centre. It will also provide a clear framework and guidance within which researchers in Singapore can pursue their work in these areas of biomedical research. ■