

Systematic Failure in a Stem Cell Fraud Case by a Poor Quality Culture

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1. Introduction

In the years 2004 and 2005, Korea became a prospective nation noteworthy in the world through the epochal development of genetic engineering in our country. Obstinate or incurable diseases were expected to be healed in a few years by a Korean geneticist. So many worldwide patients of obstinate or incurable diseases took notice of the research outcomes and organized an aid association to collect supporting funds. World renowned journals such as 'Nature' and 'Science' published Dr. Hwang's theses. A long and distant way remedy to obstinate diseases seemed to be closer at hand so early.[1]

However, a stem cell fraud case emerged throughout the world in late 2005, the pride of the Korean people was destroyed. With this as a momentum, voices of self reflection by scientific circles were raised.[2-3]

The purpose of this study is not in finding the truth of the stem cell research but to propose an effective management and control measures for the future in planning, implementing, monitoring and evaluating large scale national R&D projects in order to prevent a recurrence of this kind of failure.

2. Ethics and Quality Culture in R&D

The stem cell fraud case caused considerable damage to the public trust for researchers because most people believe that scientists always have scientific thoughts and they are usually faithful and honest by nature. Lack of ethics and poor quality mind by the researchers are not the responsibility of themselves but the result of 'rule of thumb' research environmental and management infrastructures without an adequate systematic approach. Top management of the research organization should understand the every research work has processes which are diverse case by case. He should assure that division of responsibilities will be clearly defined and method or procedure of research work should be prescribed in the research plan, prior to the start of a project.

3. Main Issues and Causes

Ironically the Case was disclosed by mass media that ballooned Dr. Hwang as a prospective candidate for Nobel Prize. The Government was responsible for the Case, too. Dr. Hwang might be heavily burdened by the sudden increase of research funds from 1.8 billion Won

in 2004 to 20 billion Won in 2005, and he might be pressed psychologically for an achievement of the research outputs in a very short term. Many scientists had worried about the sudden fund raising and all-in to Dr. Hwang's project.[4]

The science circle was confused at first time and shortly after realized the situation had gone wrong.

Top issue of the Case was on the use of illegal ova first but it expanded to the inflation of research outcomes. But, about 30 co-authors didn't know it was inflated. It could not happen if the peer review process was adapted on the thesis prior to the submission for the publication. Co-authors said differently to one another and it seemed to be because it was a leading project by a few key persons without a clear definition of the project objectives, division of responsibility (DOR), process descriptions and the reporting hierarchy of the project organizations

Some test samples were contaminated or damaged by an inadequate laboratory environment, and some of them were suspected to be substituted intentionally by certain researcher(s). But, none of them were reflected in the thesis published. Morality of the researchers is being suspected, which causes fatal damage to the public trust on research outcomes.

Further details are categorized and summarized in Table 1.

4. Preventive Actions and Solutions

To prevent a recurrence of such a Case, actions are proposed as follows:

- 1) an objective, fair and gradual funding of national research projects
- 2) clear definition of the organizational structure and the division of responsibilities in the project planning stage (eliminating reliance in a personal respect)
- 3) transparency in the acquisition of research materials
- 4) identification and retrievability control system for major research materials such as raw materials, test samples and research outputs
- 5) daily use of a laboratory notebook for the recording of research works and a daily reporting
- 6) provisions of an adequate laboratory environment
- 7) peer review process prior to publications

Consequently, the establishment and implementation of an objective research quality management system integrating all of the above mentioned elements is proposed for the future.

There are many pioneers and leading organizations who developed quality assurance guides in research and development.[5-7] The Government and science circles should give positive attention to these guidelines and try to adapt them in our research works, as appropriate.

5. Conclusion

Ethics and quality culture are most imperative to scientists and researchers for the successful achievement in R&D. Application of a comprehensive quality management system is strongly recommended for the control of major national R&D projects. Reliability of research outputs should be restored through a transparent and objective research performance.

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Table 1. Analysis of a Recent Stem Cell Fraud Case and Proposed Countermeasures

	Issue(Question)	Cause Analysis	Preventive Solutions
1	Research outcome was inflated	-Responsibility of mass media and a politic circle who ballooned in excess (A personality cult, 'solution to an obstinate disease' etc.) -Heavily burdened by the sudden increase in the research fund (1.8 billion Won in 2004, 20 billions in 2005)	-Formation of an objective and comprehensive project group excluding personal reliance -Research output verification system by peer review process -Exclude burden of short-term achievement and orient to long-term project achievement
2	Test samples might be substituted (Dr. So-and-so is suspicious)	-samples were moved personally -samples were handled without any identification and \ retrievability control.	-Setup and implementation of identification control system -Ensure traceability of sample transfer
3	Co-authors say differently (Project Leader only has keys)	-Lack of communication within the project -Project were led by distinguished persons -Lack of objectivity in research process and outcomes due to the personal management and collection of research results by the Project Leader -DOR and reporting hierarchy of project organizations were not clearly defined and implemented	-Clear definition of project organization, responsibility and authority -Establishment of comprehensive research quality management system
4	Test samples were contaminated and damaged	-Poor laboratory environmental conditions	-Perfect laboratory environment is imperative for quality research performance
5	There were no laboratory notebook (Complaint of Dr. Schatten)	-Lack of recording and reporting practice for research processes	-Establishment of system for preparation and retention of laboratory notebook
6	Illegal ova were used	-No internal criteria for the acceptance of ovum and somatic cell	-Transparency in the acquisition of research material
7	Morality of researchers is suspected	-Caused fatal damage to the public trust on research outcomes	-Ensure integrity of research output data through clear data management and recording system
8	No transparent research verification system	-No objective evaluation system for research outputs Exist (school and blood ties, regional relationships) -Political involvement ignores voice of Science circles	-Setup and implementation of internal research verification system -Introduction of independent review by external experts
General Comments		National research project performance by 'rule of thumb' in the level of private laboratory works	Introduction of an objective and transparent research quality management system is strongly recommended.