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## Contents

page

Editorial: Scientific Responsibility - Darryl Macer	33
Hwang Woo-suk Scandal Reconstructed Based on Mass Mobilization - Manjae Kim and Bang-Ook Jun	34
Teaching Ethics to Professional Scientists - Ann Boyd	38
The Principle of Autonomy, and decision-making differences between American and Chinese Cultures - Yanguang Wang	42
Concept of "Treatmentalization" - Taka Fujii	45
Shortage of organ donation resulting from difficulties in the diagnosis of brain death by medical practitioners in Malaysia - Nor Aina Mhd Khotib, Noor Naemah Abdul Rahman, Shaikh Mohd Saifuddeen, Shaikh Mohd Salleh	47
Current debates on "Standard of Care" in Research on Human Subjects in the Developing World - Zoheb Rafique	50
Deficiencies in Japan's Medical Ethics Review System - Akio Kanayama	52
A Re-examination of Organ Sale and its Challenges - Daniel J. Hurst	57
ABC16 Announcement and EJAIB Subscription	64

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## Editorial: Scientific Responsibility

This 146<sup>th</sup> issue of *EJAIB* starts with the sad saga of Dr. Hwang Woo-suk. I had the pleasure to be on several panels at international conferences with Dr. Hwang, talking about the ethical issues raised by cloning. Not known at that time was the fact, that he later admitted, and was convicted for, that he had falsified experimental data in some of his papers. He also had used eggs from donors who could not provide free and informed consent. The paper by Manjae Kim and Bang-Ook Jun, exposes in five phases his public scientific career, and retreat from fame. Bioethicists in Korea played an important

role in calling for review, and this is documented in the paper. The next paper on "Teaching Ethics to Professional Scientists" by Ann Boyd, explores how we might educate young scientists not to follow the same paths that are exposed by the famous examples of scientific fraud. Despite over a decade of teaching research ethics to all graduate students in USA, there are still significant examples of unethical practices. The same fact of unethical science is seen globally. We need more evaluation of efforts to ensure that scientists follow ethical guidelines and practices.

The concept of individual versus familial autonomy, and decision-making differences between American and Chinese Cultures is explored by Yanguang Wang. How much do people in different cultures view their public health and disease in the lens of "Treatmentalization"? This is explored by Taka Fujii. Rather than avoiding disease by our own lifestyles to minimize disease, we often view our disease as something simply to get a "bandaid" to fix. The paper calls for a more holistic and lifespan orientated view of health than the current one.

The diagnosis of brain death is an issue which is still contentious in some countries, including in Malaysia as reported by Nor Aina Mhd Khotib et al. There is a need for continued and better education on this issue. Current debates on "Standard of Care" in Research on Human Subjects are discussed by Zoheb Rafique. A detailed case report including falsification of medical records and failures in communication in Japan's Medical Ethics Review System is discussed by Akio Kanayama. The particular case described is just the tip of an iceberg, as most cases do not get reported. The questions of organ sale as discussed by Daniel Hurst. This issue is one that continuously returns to the bioethics table.

In 2016 the Asian Bioethics Association will hold its 16<sup>th</sup> Conference, in Boracay, the Philippines. This conference will be an event and training from 4-8 November 2016, and we ask people to arrive there by the 3<sup>rd</sup> November. We also will ensure that amongst the plenary sessions, we also schedule some free time for people to enjoy the Pacific ocean, or forests and nature. Significantly in the last few decade both the US and UK government have dedicated large areas of the Pacific Ocean as Nature Reserves. So have some of the sovereign states in the Pacific. It is also a good occasion to discuss ocean and water ethics, along with all the usual issues of cross-cultural bioethics (see the back page).

The new ABA Board looks forward to meeting itself and many readers there. This year is twenty years since the 1995 Asian Bioethics Conference in Beijing, which led to the ABA. It will be the first time the ABC is held in the Philippines, so we hope to see many colleagues there.

- Darryl Macer

# Hwang Woo-suk Scandal Reconstructed Based on Mass Mobilization<sup>1</sup>

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## Abstract

This article reviews the notorious Hwang Woo-suk scandal based on a mass mobilization perspective showing three features of mass-ness, cathartic expressivity, and communicative orientation through transmissions by the media. Following the process of mass mobilization such as period 1: the beginning of Hwang's hype, period 2: the heyday of Hwang's success, period 3: chaos, period 4: national turmoil and Hwang's downfall, and period 5: final, it tries to show how the cooperation among three actors including Hwang, media and the Korean government appealed to the Korean people's emotions and nationalism in dealing with science.

## 1. Introduction

Hwang Woo-suk became world-renowned in the field of embryonic stem cell research after he published two articles in *Science* (1, 2). Because he was perceived as a national hero, his fabrication of scientific data revealed in November 2005 tremendously shocked the whole Korean society. The scientific fraud is nothing new in the history of science (3). However, it is rare to find any comparable case with the Hwang Woo-suk scandal in its impacts that a single scientific misconduct can create.

It is well known that media and the Korean government as well as the scientist himself were all responsible for this scandal. Media received Hwang's claims without any substantial data, and mythified him as a figure to conquer incurable diseases (4) and to bring South Korea immeasurable economic prospect from his promising research (5). The Roh Moo-hyun government suffering from the lack of popular support promoted an exemplary policy success by backing up Hwang (6). Until the very last moment, president Roh affirmed his unflinching support for Hwang (7).

This paper claims that the cooperation among three actors including Hwang, media and the Korean government resulted in mobilizing the public to believe the rosy future by appealing to the Korean people's emotions and nationalism rather than to scientific rationality. As a result, even when the evidences of deception revealed, the public resisted to believe scientific facts. Some frantic followers demonstrated to defend Hwang.

Since a final court decision was made nine years ago, the movie, *Whistleblower*, based on the Hwang Woo-suk scandal, was made and was a box office hit in 2014. It has taken almost a decade for Korean society to reconstruct this sensational social hypnosis in a mass friendly form.

## 2. Mass mobilization

Mass mobilization is historically utilized by facists to win popular support and consolidate their power. Facists used mass meetings, parades and other gatherings to create patriotic fervor, and appeal to people's emotions rather than to their reason (8).

In some democratic countries, mass mobilization is sometimes called a demonstration. In spite of relatively weakened fanatic enthusiasm, it still shows three features of the mass mobilizations, its mass-ness, its cathartic expressivity, and its mediated, communicative orientation (9). More specifically speaking, it first visibly demonstrates that a large number of people share a common political sentiment. Second, the event must have 'energy'-and preferably a lot of it-to engage emotionally both the people who are there and those who are watching at home. Lastly, the communicative impact of the message and the 'energy' is realized through transmissions by the media, so the event's form must be mediagenic.

Therefore, social movements need to be situated in a dynamic relational field in which the ongoing actions and interests of diverse all influence social movement emergence, activity and the outcomes (10).

## 3. Hwang's scandal

Hwang Woo-Suk was a professor of theriogenology and biotechnology at Seoul National University (dismissed on March 20, 2006). He rose to a national hero after claiming a series of remarkable breakthroughs in the field of stem cell research. His works were best known for two articles published in *Science* magazine in 2004 and 2005. However, both papers have been editorially retracted after being found to contain a large amount of fabricated data (11).

## 4. Process of mass mobilization

Hwang's scandal reconstructed into five periods reveals how Hwang, the Korean government and media have emotionally affected the Korean people at the beginning and counter groups including "PD Notebook" and rational scientists confronted manipulations at Hwang's papers in the late period.

### Period 1: The beginning of Hwang's hype (Feb 1999 – Jan 2004)

<Hwang>

Hwang began to receive media attention as he announced that he succeeded in creating a cloned dairy cow in February 1999 (12). He failed to provide scientifically verifiable data for the research, giving only media sessions. After two months, he again claimed the success of cloning a Korean cow without scientific evidences (13).

During this period, Hwang's research areas remained in creating genetically-modified livestock and claimed several scientific achievements which were not verified, and promised cloning some other animals including a Siberian tiger to get sensational attention (14).

Hwang also sought to establish a tie to political and economic institutions. He approached Park Ki-young who was appointed as the Information, Science and Technology Advisor for the President, and put her as one of the co-authors in his 2004 Science paper. Through ties with Park, he could build a favorable environment in the government, including Kim Byung-joon, Chief National Policy Secretary, and Jin Dae-jae, Information and Communications minister (15).

<Media>

Hwang's several claims were well received by the media attracted by Hwang's claim of immeasurable economic prospect. With the lack of professional reporters in the field of science, the media delivered Hwang's own words without any other verification (16).

<sup>1</sup> Part of this paper was presented at the 2006 Annual Meeting of 4S, Vancouver.

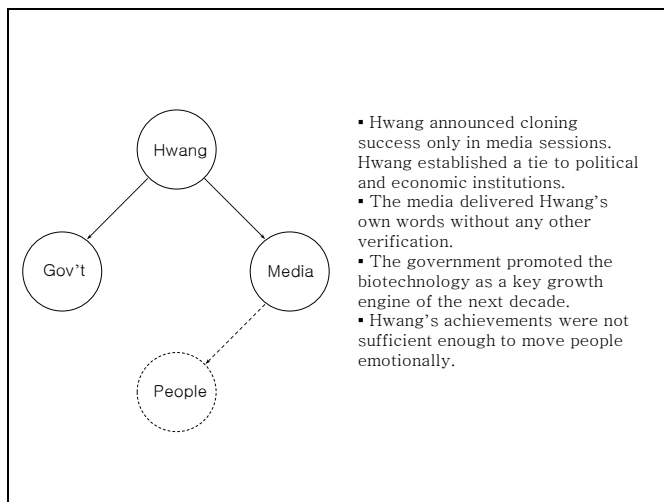
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## &lt;Government&gt;

Hwang presented a report on his recent successful cloning of a cow to President Kim Dae-jung as a part of major state-funded research and development projects (17). But it was from the Roh Moo-hyun government that Hwang especially tried to win favor. Suffering from a lack of popular support, President Roh wanted to demonstrate his competency by creating and promoting an exemplary policy success. For this purpose, the government decided to promote the biotechnology as a key growth engine of the next decade (5).

## &lt;People&gt;

People were exposed to positive media reports about Hwang. However, his self claimed achievements were not sufficient enough to move people emotionally.



Period 2: The heyday of Hwang's success (Feb 2004 – Oct 2005)

## &lt;Hwang&gt;

While much of Hwang's previous work conspicuously lacked any supporting paper, his studies were published and were hailed as a major advance in the field during this period.

First, Hwang and his team announced that they had successfully created the world's first human embryonic stem cells from cloned human embryos in February 2004, and published their paper in the March 12 issue of *Science* (1). Hwang's team again claimed to have developed the world's first human embryonic stem cells tailored to match the DNA of individual patients (2). The results were published in *Science* in May 2005. According to Hwang and many other scientists, it would be possible to use stem cells to generate healthy tissue to replace that either damaged by trauma or compromised by disease (18).

Hwang was appointed to head the new World Stem Cell Hub, a facility that was to be the world's leading stem cell research center in October 2005 (19).

Hwang's team succeeds in developing Snuppy, the world's first cloned dog. The work was published in *Nature* in August (20).

## &lt;Media&gt;

During this period, too, the media continuously delivered Hwang's words faithfully (21). Although they reported ethical questions raised by the *Nature*, they were not interested in mentioning any negative remarks about Hwang (22). Hwang was a rare scientist who could explain his research in ordinary words, and provide visions and dreams (23). The media were eager to mythify him for his tireless devotion to

his research. Hwang's remark that he and his team's weekly work schedule consisted of "Monday-Tuesday-Wednesday-Thursday-Friday-Friday-Friday" decorated headlines (24). Through the media, Hwang was reborn as an untouchable world famous national hero (25).

## &lt;Government&gt;

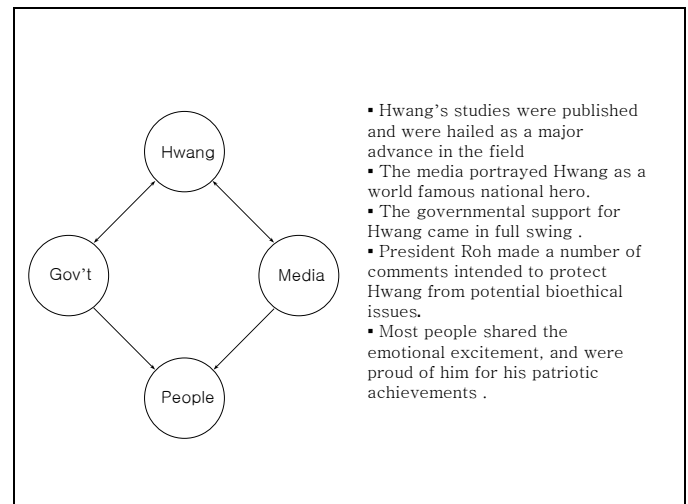
After Hwang's so-called groundbreaking paper was published, support for Hwang came in full swing. The government launched a pan-government task force to financially support Hwang. Hwang was registered as an important national figure and guarded by police and state intelligence agents. In June 2005, the Ministry of Science and Technology selected Hwang as the first recipient of the title Supreme Scientist, and honor worth US\$15 million (26). The national post office issued post stamps commemorating Hwang's success (27).

President Roh made a number of comments intended to protect Hwang from potential bioethical issues, "It is not possible nor desirable to prohibit research, just because there are concerns that it may lead to a direction that is deemed unethical" (28). "Politicians have a responsibility to manage bioethical controversies not to get in the way of this outstanding research and progress" (29).

## &lt;People&gt;

People consider Hwang as a national hero. Especially to those with incurable illnesses or their family members, Hwang was their hope and reason to live (25). Private companies and individuals poured donations for Hwang's research. Korean Air Co. provided Hwang with complimentary travel on any of its domestic and international routes (30).

Although some religious organizations and experts in bioethics voiced opposition to the cloning research on embryos performed by Hwang, most people shared the emotional excitement, and were proud of him for his patriotic achievements (25).



Period 3: Chaos (Nov 2005)

## &lt;Media&gt;

During this period, the media were sharply divided. On one hand, "PD Diary", a popular MBC-TV investigative reporting show, raised the possibility of unethical conduct in the egg cell acquiring process, which was the first media attempt questioning Hwang's ethical violation (31). On the other hand, despite the factual accuracy of the report, other media still showed unwavering support for Hwang (32).

As a wave of campaigns to save Hwang from an ethics scandal swept the nation, the MBC television network faced sharp criticism and financial losses (33).

#### <Hwang>

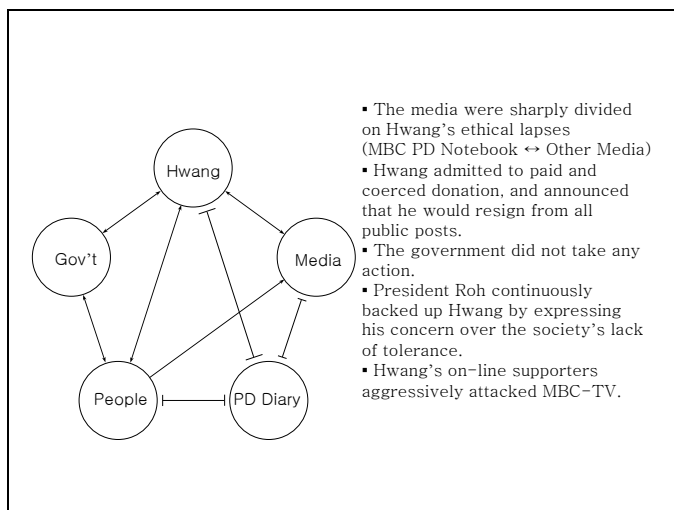
Until November 2005, Hwang was criticized only for unpublicized ethical violations. During this period, however, Hwang encountered an obstacle that he had paid female donors for egg donations and that he had received donations from two junior researchers, both of which were violations.

First, Gerald Schatten, a U.S. professor at the University of Pittsburgh and a partner in Hwang's research, said he had cut all ties with Hwang out of suspicions of unethical research conduct on Nov. 13, 2005 (34). Following an intense media probe, Roh Sung-il, one of Hwang's close collaborators and head of MizMedi Women's Hospital, held a news conference on November 21, admitting that he compensated donors of the ova used in Hwang's stem cell research, while stressing that Hwang had no prior knowledge of this (35). Next day, South Korean TV network MBC broadcasted a program that included strong evidence that Hwang's team had used ova extracted from its junior researchers (31).

On November 24, Hwang admitted to ethical lapses and announced that he would resign from all public posts. However, he denied coercing his researchers into donating eggs and claimed that he found out the situation only after it had occurred (36).

#### <Government>

The government did not take any action. A top official of Korea rebuffed a claim by the *Nature*, which urges the government to launch a probe into how Hwang obtained eggs for his stem cell research (37). In spite of Hwang's ethical violation, President Roh continuously backed up Hwang by expressing his concern over the society's lack of tolerance (7).



#### <People>

Many speculations accumulated around the US scientist's withdrawal from the joint cell project with Hwang. Some conjectured on a conspiracy theory that the US wanted to block another country from taking the initiative in an important scientific and technological field (38).

Everyone more or less operated under the assumption that the MBC show was at fault and not Hwang. People were mobilized to assert that criticism of Hwang's work was unpatriotic. Hwang's on-line supporters aggressively attacked MBC-TV. The MBC site was inundated with thousands of hate messages. After the program was aired, some demonstrated in front of the network headquarters. As a result, the major

companies who sponsored the show had to immediately withdraw their support (39).

Sympathy for Hwang resulted in an increase in the number of women who wanted to donate their eggs for Hwang's research (40). Over two thirds of those responded to the Korea Times' online poll said they would continue supporting stem cell pioneer Hwang, irrespective of the recent ethical controversies involving his research. A majority of Koreans thought little of Hwang's ethical breaches and paid attention only to Hwang's achievements (41).

#### Period 4: National turmoil and Hwang's downfall (Dec 2005)

##### <Media>

PD Notebook planned to air its second report on the "myth" of Hwang as soon as possible, this time focusing on validity of the patient-specific stem cells (42). However, the all-news cable channel YTN televised that one of Hwang's researchers from MizMedi was coerced by illegal means to testify against (43). The scheduled broadcast was canceled and MBC-TV had to make a public apology to the nation. MBC confronted the most serious crisis since its establishment, making a decision to put weekly news magazine "PD Notebook" on hold indefinitely (44).

##### <People>

While some began to denounce Hwang's research, Hwang's loyal supporters participated and showed more aggressive mobilization than before on-and off-lines. A website backed by Hwang's supporters began taking egg-donation pledges online. Hundreds of South Koreans offered to donate eggs for stem cell research in a show of support for Hwang despite his admitted ethical breaches. Members of an online community "I love Hwang Woo-suk" queued up next to a road of azaleas from the entrance of the Seoul National University's veterinary medicine college building to Professor Hwang's office to symbolize their wishes for Hwang's return (45).

##### <Internet groups of scientists>

By contrast, the internet groups of scientists questioned the authenticity of the stem cells, including BRIC (Biological Research Information Center), SCIENG (Scientists and Engineers' community) and DC Inside Science Gallery. A member of BRIC, a website dedicated to biologists, first discovered the discrepancies in DNA analysis data in Hwang's paper and made them public. Other members followed suit, uncovering the fact that many photos presented in the paper were also fabricated. The Science Gallery of DC Inside, a website for digital camera enthusiasts, also contributed to the revelation of Hwang's misconduct by discovering more problems in the paper and pointed out fallacies in Hwang and his supporters' claims. Because these on-line boards were operated anonymously, contributors could express their opinion freely. Furthermore, members' comments were too professional for Hwang's supporters to attack. Young scientists played a pivotal role in pinpointing manipulations at Hwang's papers (46).

##### <Government>

The Ministry of Health and Welfare denied Impropriety of Hwang's research and President Roh expressed his support for Hwang, saying that "*We'll continue to support Professor Hwang. We hope he will return to his research lab soon for the sake of people with physical difficulties and the public.*" (7)

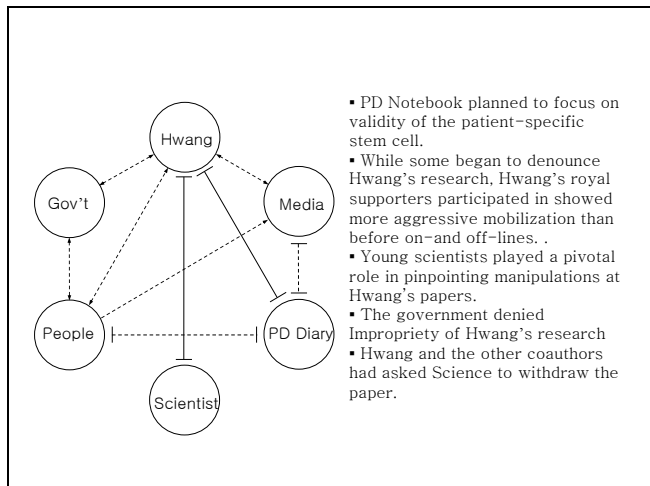
##### <Hwang>

During this period, Hwang was accused of scientific misconduct. The scandal took a dramatic turn on December 15, when Roh Sung-il, who collaborated on that paper, stated

to media outlets that nine of eleven lines had been faked; specifically, DNA tests illustrated that those nine lines shared identical DNA, implying that they had come from the same source. Roh stated that "Professor Hwang admitted to fabrication," and that he, Hwang, and another coauthor had asked *Science* to withdraw the paper (47).

#### <Seoul National University>

Junior researchers at Seoul National University (SNU) urged the school's panel to conduct an inquiry. SNU appointed a committee to investigate whether there was misconduct in stem cell research carried out by Hwang (48). The SNU investigative panel determined that the production of nine patient-tailored stem cell lines was a fabrication (49).



#### Period 5: Final

##### <Hwang>

On 12 January 2006 Hwang held a press conference to apologize for the entire fiasco, but still did not admit to cheating. Instead, he explicitly put the blame on other members of his research project for having deceived him with false data and alleged a conspiracy, saying that his projects had been sabotaged and that there was theft of materials involved (11).

Hwang was indicted on 12 May on charges of fraud, embezzlement, and violations of the Korean Bioethics Law. Five other members of his team have also been indicted, three on fraud charge, one on a bioethics law violation, and one for destroying evidence and obstructing business operations. In addition to research misconduct, the prosecutors claim Hwang misappropriated USD2.99 million in state funds and private donations (50).

##### <Government>

The government says that it will try to retrieve the grant money given to Hwang and his lab at Seoul National University. Among top officials, no one took any responsibility for financially supporting Hwang's projects (51).

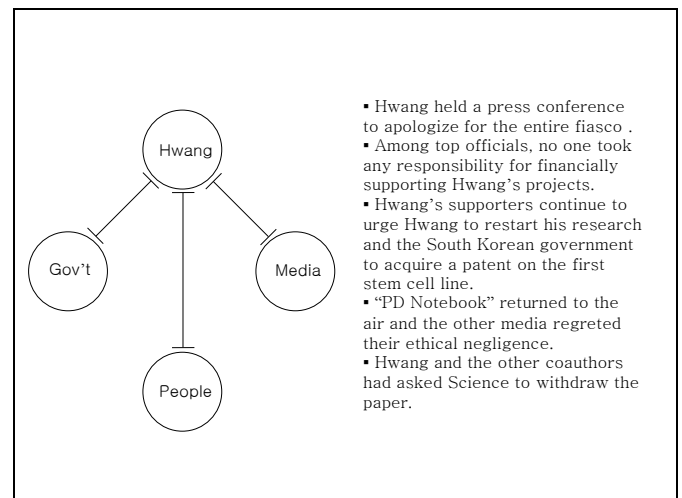
##### <People>

Hwang's supporters continue to urge Hwang to restart his research and the South Korean government to acquire a patent on the first stem cell line. Hundreds of Hwang's supporters gathered in front of the prosecutors' office, protesting Hwang's indictment (52).

##### <Media>

The investigative journalism show "PD Notebook" returned to the air on January 3, 2006 and summarized the course of Hwang's scandal until that day. The show had been cancelled in retribution after it aired its momentous show that correctly

accused Hwang of oddities in his research on 22 November 2005. Their last show of the year on November 29 covered other topics. It remained off the air for 5 weeks (11).



#### 5. Conclusion: mobilization and science

Hwang's scandal portrays all three characteristics mentioned earlier.

1) mass-ness: Since period 2, almost all Koreans shared a common sentiment believing in Hwang.

2) emotional expression: Whenever Hwang was criticized, his supporters mobilized all resources to protect him. They refused to hear and understand evidences against him to the very last moment. They asserted that any criticism of Hwang and his work was unpatriotic.

3) Media: Media played an important role in making the scientist a national hero. The media glamorized the story, appealing to the emotions and patriotism of the people, fueling hopes that his research may truly bring about magic.

Besides these three, this case is unique in terms of its heavy dependence on the internet. Although Hwang's supporters sometimes demonstrated in a traditional way, resource mobilization through on-line was widely used regardless of people's different opinions. Especially internet groups of scientists solely depended on on-line boards.

To conclude, people's emotional demonstrations and activist movements were results of the "media play" of the three parties: Hwang, government, and media. Ironically, however, it was media that confronted three allies and extricated the Korean people from irrational massive hype.

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## Teaching Ethics to Professional Scientists

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### Abstract

Supporting the view that ethics can be taught, this paper will explore the frequent lack of a philosophical foundation in scientific training and its impact on a course on 'Science and ethics.' The incidence of cases of misconduct by scientists engaged in basic research led the United States to establish the Office of Research Integrity. Their publication, *"Introduction to the Responsible Conduct of Research"* covers the ethical conduct of research and defines misconduct as fabrication, falsification and plagiarism. Concern for breach of public trust with repercussions in scientific funding has led to mandates courses in ethics for students training for scientific research careers. Having concentrated their course work in laboratory-based science, these students have less familiarity with philosophy and consequently struggle with the ethical reasoning aspects of a course in science and ethics. Discovery of a therapeutic drug or device opens a complex web of regulations by Food and Drug Administration for the ethical use of human subjects. Again the ethical system is one of rules and conduct based norms without foundational philosophical support for the ethical principles used in the guidelines. Rules of law reflect corrective action. Engaging students in case studies helps alert them to potential ethical dilemmas and invites them to explore why one action is right, good or better than an alternative. Narrative ethics provides a human presence to competing and compelling claims, the intersection of which is the ethical issue and concept. Dissection narratives help students explore how ethics can be taught and learned in a pluralistic society and remain relevant to the field of expertise they have chosen. The challenge lies in finding the best methods for teaching ethics in a particular discipline. Is there a code of ethics that applies cross-culturally and across disciplines? Early and often should be the mantra of teaching ethics throughout the development of the individual and emergent professional.

### Introduction

Graduate students who work in scientific research or related biotechnology jobs are trained in the scientific method, critical thinking, and analytical skills which help them in laboratory based studies. Controlling for variables and being open to affirmation or rejection of the working hypothesis is

central to the scientific method. Concentration on foundation and elective courses to build laboratory skills may result in a minimal number of electives in the humanities such as political science, history, or philosophy.

The United States Office of Research Integrity (ORI) was founded in 1989 to reduce instances of scientific misconduct under the auspices of The Public Health Service (PHS). A training document was released containing exercises to use with students to prevent misconduct (Steneck, 2000). The government requires that every institution receiving PHS funding have procedures to handle allegations of misconduct. Academic institutions receiving government funding are required to train scientists in proper conduct, with the aim of reducing the incidences of scientific misconduct (fabrication, falsification and plagiarism). This mandate has translated into various courses on "research ethics." I offer a graduate course within the Master of Science Program in Biomedical Science entitled "Science and Ethics." Having taught this course in various permutations for over fifteen years to hundreds of students, I extract from this experience some broad implications for teaching applied ethics.

### What is ethics?

For the purposes of this paper, ethics is a decision making paradigm that relies on philosophical foundations about what is good for individuals and communities. As a branch of philosophy, ethics focuses on right action, or a reasonably justified action that is at least as good as any alternative action. Aided by a set of rules, principles, norms and values, ethical reasoning imagines alternative actions for a given set of circumstances, discerning among the options the better or best of the alternatives. Ethics as moral philosophy analyzes concepts such as goodness and moral truth. An ethical choice is acceptable to the larger community and based on culturally accepted norms and values and may become codified in guidelines or laws (Penslar, 1995).

It may be that people develop a sense of right and wrong early in life, during childhood at the instruction of parents and elementary school teachers, or so students often assert. If it is true that every person develops a moral compass along with strong bones and muscles, ethics education would be purely academic and unnecessary. However, if one does not inherit a moral code, or acquire one naturally in the course of primary education, then ethics must be taught and the pregnant question is how to teach ethics in professional disciplines.

The danger addressed by the ORI for awareness and prevention of misconduct is appropriate because scientific research is a matter of public trust. It is a challenge to translate complex scientific knowledge into useful terms for the good of the public. If and when data is manipulated for individual or corporate gain or misconduct pollutes truth and trust, the public becomes skeptical of the results and potentially of scientists.

Research ethics is not limited to biology but is the domain of investigation – search for knowledge in any discipline. Plagiarism is relevant for all writers. Conflict of interest is not exclusive to science or scientists. We live in a time when information is available at our fingertips through numerous electronic devices. Assigning proper credit to an idea or person is important for every author. The speed and easy access to information today may so flood our senses that it is more likely we will neglect to recognize and attribute our sources.

A set of professional ethical norms or rules directing behavior should reflect the cultural values of the society unless we allow diverse disciplines to create their own ethics norms, which pushes the ethical relativism card to the limit and risks loss of all social cohesion. Listening to students

over the years has alerted me to the fact that social forces shaping our ethical norms are strong but individual students who are aware of their own strong desire to succeed acknowledge the counterweight of wealth, fame and power. Students often appeal to a relative or situation sensitive analysis. If the norms that guide behavior are relative to culture and/or discipline, the emergent problem is that we lose a sense of the commons as the social good within which individuals flourish. If students are strong proponents of ethical relativism, they find practical ethics, as the norms of a professional praxis, unpersuasive. This raises the question: can ethics be taught, generally, and if so is there any difference when the students are already engaged in a professional discipline?

One way to look at teaching is to think of conveying knowledge from generation to generation. Systems of morality are collective acquisitions, built up in various cultures over millennia. Emphasized in social units such as family, schoolrooms, and beginning with the simple maxims e.g. lying and stealing are wrong, such values are communicated between generations. Social norms or values aim at social and moral order. *"Bioethics is a universally important subject, fully consonant with a liberal arts and science education, and as such it should not be taught first, let alone only, at the professional level"* (Lee, 2013).

It may be that there are graduate students in science who have never given much thought to the moral aspects of their behavior. If we have a pessimistic attitude about human nature, we may rely on regulations designed to correct and prevent misconduct. When rules become guidelines those who adhere to them must recognize their value, or at least accept the punitive impact of infringement. Compliance as obedience to the rules can give a false sense of safety, especially if the ethical reasoning grounding the rules is not apparent or understood. Asking why is a central tool of ethical reasoning.

For the daring professor of science and ethics there are tools available and it may be important to not overstate one's goals. One course in genetics will not make a student a professional and productive geneticist, nor will one course in ethics make students ethical for life. What one course can do is explore the range of positions a scientist may find herself in during a career, especially one with divergent paths each of which may carry unique ethical challenges. Teaching and doing research differs widely between the research conducted in academia and that done for a private firm. Students may learn from a mentor about the subtle points of data recording, analysis, reporting, authorship, peer review and funding. Company codes may require different formats for data recording and have restrictions on proprietary information about when and if it can be published. Practicing scientists are ideally suited to sharing with those in training the various demands, pressures, temptations, and advantages to scientific conduct that promotes integrity and success (Penslar, 1995).

### Reducing cases of misconduct in Science

It may be that cases of misconduct are reported more frequently as a result of increased awareness born of research ethics courses. David Wright, director of the ORI, reported that in 2012 more than 400 allegations of scientific misconduct were received, double the number from the preceding year (Wright, 2013). Among students expected to study ethics – science students for example – current education is not meeting expectations. Responsible conduct of research (RCR) promoted by the ORI through training courses describe forms of research misconduct. It would be difficult to show that such a course reduces misconduct which is reported at the rate of one incident per 100,000 scientists

per year (Plemmons, 2006). While the goal of reducing research misconduct may be hard to document other goals are measurable, such as knowing the expectations set forth in the guidelines.

A study conducted to explore how common misconduct is among U.S. scientists revealed that over 33% of the several thousand scientists surveyed admitted to one or more forms of misconduct. For example, 15% dropped data points from an analysis on the basis that they had a gut feeling the data points were inaccurate; 15% changed the design, methodology or results of a study in response to pressure from a funding source; and 10% said they inappropriately assigned authorship credit (Martinson, 2005). Martinson's survey data suggests more misconduct is taking place than is either reported or recognized and it is this reality that courses in science and ethics are designed to correct.

The high profile misconduct cases such as the hoax that the MMR vaccine (measles, mumps, and rubella) is associated with autism garners so much attention that there is a risk of not paying attention to "minor" cases of misconduct (Wakefield, 1998). Despite the fact that 10 of 13 authors retracted their interpretation of the findings in the *Lancet* article, the association continued to be accepted by parents resulting in lower vaccination rates of children. The General Medical Council of the UK ruled that Wakefield had acted unethically and *Lancet* retracted the paper. The British medical Journal's editor in chief said in a news release: "The MMR scare was based not on bad science but on a deliberate fraud. Such clear evidence of falsification of data should now close the door on this damaging vaccine scare."

What is the current rate of MMR compliance? CDC reported on vaccination coverage among kindergarten children in the U.S. in the school year 2011-2012 that MMR vaccination was 94.8% among 47 reporting states. While the overall vaccination rate is good, local areas where vaccination rates were lower experienced 17 outbreaks of measles with 222 cases among unvaccinated persons (MMWR/CDC, 2012). It is true that measles is a childhood disease from which most children recover without harmful consequences, but not all. Humans are the only reservoir of the virus with 30-40 million cases per year globally with 1-2 million deaths. The vaccine (MMR) is effective (In 1941 there were 894,134 cases of measles in the US, and in 2013, 113 cases with 99% of those cases occurring in unvaccinated children). There are serious complications of progressive neurological degeneration albeit rare, but severe enough to justify the vaccine. Measles is the leading cause of vaccine-preventable deaths in children less than five years of age. It is regrettable that parents think they have to choose between trusting a vaccine to protect their child against a viral infection and trusting a scientist to warn them of harm from that vaccine.

The deceptive linkage of vaccination and autism demonstrates how integrity in science is vital to public trust. Sadly the media amplification of the study made it difficult to correct when the hoax was revealed and corrected in the normal process of peer review. Retraction by the authors of the *Lancet* article did not reach the attention of the media or the parents who were inclined to not vaccinate their children. If only a few in a community are not vaccinated, collective immunity protects the few who are vulnerable. This example illustrates why science and ethics should be taught.

#### Course format

Courses designed with an emphasis on case analysis and discussion among participants consistently shows stronger understanding of the norms of ethical conduct, over a more didactic approach (Brown, 1998, Plemmons, 2006, Powell, 2007). One published study surveyed students about their perspectives after completion of one of eleven different

research ethics courses at ten different institutions. Undergraduate and graduate students enrolled in these courses. The students received a voluntary anonymous survey from their instructor after completing the course. Seventy-seven percent of open ended responses listed kinds of information learned, with 75% of the respondents noting that the course was useful in preparing them to recognize, avoid and respond to research misconduct. The majority reported better understanding of what was expected but no significant impact on their individual attitudes (Plemmons, 2006). These results suggest that such courses increase awareness but raise the important question of whether awareness converts to more ethical conduct.

Plemmons and Kalichman surveyed 50 RCR instructors from 37 different institutions about their goals for teaching skills in their courses. Responses varied widely, "from a focus on teaching the skill of ethical decision making to the perceived importance of ensuring that trainees understand the importance of the community in some research relationships" (Plemmons and Kalichman, 2013). The responsible conduct of science requires diverse skills: the ability to conduct research, design experiments, record data, cite resources, write papers, manage stress, and have the ability to recognize ethical issues and make ethical decisions based on moral reasoning. It is difficult to measure all these skills and course objectives aiming at them. Results of the survey by Plemmons and Kalichman suggest that "ethical decision making" and "critical thinking" are skills given highest importance in the RCR courses taught by the respondents, but teacher expectations varied widely. Interestingly many of the respondents expected students to have critical thinking skills prior to their RCR course. In answer to "what goals do you have for teaching the skill of ethical decision making?" one respondent answered "none" (Plemmons and Kalichman, 2013).

#### Ethics for a career in science

The content of my course, Science and Ethics, has evolved from focusing on the misconduct ORI material to an expanded effort to cover various ethical challenges at different stages of a scientific career. A scientific career may diverge from basic research into clinical trials involving human subjects. A scientist may be asked to serve on an ethics review committee, or be a peer reviewer for a journal or funding agency. Each of these stages in the development and practice of the profession have ethical relevance. The course therefore includes sections on career choices, and ethical intersections at various stages of professional development. Knowing that I, the teacher, cannot follow students throughout their careers, it is my intent to provide an ethical toolkit to take along on their journey.

The first segment deals with proper conduct, why misconduct is harmful to one's own career and potentially damaging to science and society. A series of cases illustrating why and how to maintain data records, ways to retain an objective perspective in data analysis, shared responsibility in assigning authorship in publications, journal expectations about peer review and the scientific community's trust in peer review to certify and validate the integrity of research findings. It is important that students pursuing a career in science understand why misconduct is harmful to them individually and to the larger realm of scientific knowledge. Cases in which the student can relate a question posed about what should or should not be done help clarify the nuances of plagiarizing ideas and concepts, who and what to attribute, as basic norms of honesty and trust.

Stress may be the primary cause of misconduct and an ethics course will not remove career stress, but awareness can help students create ways to deal with it. A commitment



to the overall value of science for the public good, the trust the public places in scientists to advance medicine and technology for the benefit of life can help counter-balance temptations to falsify data, adjust experimental protocol, or yield to external pressure. Teaching students to take time to get an objective and fresh look at a situation and discuss the situation with a dialogue partner can help. The benefit of conversation is modeled in small group discussion of cases followed by having each group feedback their decisions, where they had agreement, where they disagreed, what they learned from one another, and if anything in the case scenario surprised them. Comparing and contrasting the feedback from a collection of cases carefully chosen to represent the situations that could lead to misconduct helps increase awareness and helps students articulate what they should do in such situations.

A guideline set of rules or norms for proper conduct of a research scientist seems straightforward – almost intuitively obvious. Rules of conduct are like steps in the protocol of an experiment as a step by step instruction in what to do and when. Students struggle with the why questions: why should all the data be reported? Why must all contributors be cited? What value does negative data have for scientific progress? These questions require more thoughtful reflection and reasoning, which often causes frustration.

Case study and narrative help hone the student's understanding of ethical reasoning in the context of scientific praxis. It may be difficult to wedge a book on justice into a single course on ethics and science, but it is simple to construct a narrative about selective authorship on a publication. A student who works hard to gather data and finds himself omitted from the authors of the resulting paper will immediately see that the practice was unfair. It may be difficult for a student to understand why throwing out some data believed to be a product of experimental error is wrong until the larger problem of not reporting negative data results in harm or misdirection in research. I use selected cases from "Case Studies in Biomedical Research Ethics" by Timothy F. Murphy (2004) with a variety of examples of study design, conflict of interest, authorship and publication, and social effects of research.

In a second section of the course, I compare the norms of research with the guidelines for clinical research, because a research scientist would be very happy to have a discovery proceed to a therapeutic intervention. Should the scientist desire to shepherd the drug or vaccine through clinical trials, an entirely new set of ethical norms and regulations emerge. Many of these regulations are born of historical cases of subject abuse...what could be described as clinical misconduct. Reading about cases that failed to consent participants, or trials designed with a placebo when a proven therapeutic drug was available but unaffordable in the geographical context of the trial, helps students identify why the guidelines stress informed consent as respect for the participants as persons, why the risks and benefits for the putative subject should be ethically evaluated in the design of the trial and why inclusion and exclusion criteria can limit access (justice) or so circumscribe data obtained that general applicability, safety and efficacy is limited to those who fit the test subjects profile. Small groups of students discuss a variety of cases and their feedback as with the cases on misconduct in research, are reported to the entire class generating broader discussion (Dunn and Chadwick, 2001).

The third section deals with roles scientists could or might play in broader social discourse on contemporary topics, such as genetics: preimplantation genetic diagnosis, selection and enhancement. Science uses a vocabulary specific for disciplines such as genetics. What a geneticist understands about genetic pathways must be translated for the average

consumer in order to bring the issues forward for public debate. Public policy guidelines emerge from recommendations made by panels of ethicists and scientists reasoning together. Larger public debate is helpful where restrictions in funding or social prohibitions emerge where consensus is impossible. I assign a series of ethical articles for and against genetic diagnosis for late onset genetic diseases and selected articles that are for and against efforts to genetically enhance offspring, in order to capture the philosophical grounding each author uses for their position.

### **Philosophical Foundation**

Helping students find a moral compass, a grounding of why one ought to behave in ethical ways in their profession and more generally in life is challenging. For many years, I appealed to moral theories as a grounding point for ethical reasoning, selecting a consequentialist approach, because it was likely that students would relate to a rules - based approach. Some students are open to recognizing the rewards or punishments as consequences when rules are upheld or broken, but most are resistant to seeing themselves as morally culpable. Students focus on their individual opinion and values, not because they are universally valid but because they believe their morals are their own, learned in childhood. Increasingly students insist that ethics is relative, embracing a strong sense of tolerance for diverse value systems.

Having tried to teach the contours of consequentialist utilitarianism, respect for persons as teleological or ontological arguments to ground an ethical choice, I find students less and less willing to stick to any theory or set of principles for every situation, case or narrative. The voices claiming, "It depends" become louder by the semester. In the context of students without prior courses in philosophy and already engaged in a scientific career, narrative ethics has become more and more appealing.

Narrative ethics uses stories that provide ethical insight and wisdom for action without appeal to ethical principles, rules or maxims or narratives that support and expose the ethical wisdom embedded in principles, rules or maxims (Brody and Clark, 2014). Well-chosen stories communicate values and actions, and demonstrate moral virtue. By critiquing and comparing stories students are helped in the discovery of what values they resonate with and encounter desirable virtues they may choose to develop.

Narrative helps embody ethical dilemmas: real characters in real situations wrestling with real decisions. Students repeatedly assert that there are no universal rules or standards or principles that address every conceivable ethical dilemma. When students cluster in small groups to discuss a case they start with an intuitive sense of right and wrong, and they make moral claims based on the values they have acquired thus far in their lives. They do not all start at the same place, and hearing what someone else thinks often leads to a reinforcement of their starting position. Talking about the case does not immediately give way to consensus, but it exposes the contours and conflicts of the ethical case (Lantos, 2014).

Trying to explain why one answer or response to a case is good or better than another exposes a lack of overall conception of the good. If each student can freely express his or her idea of the good, and suggest an action as a free autonomous agent, we are left with silence because each student is their own judge of right and good. Such plurality reflects a cultural arc toward relativity and away from universal or absolute ethical normative philosophy. No one moral authority has the ethical trump card in today's debates. So how do we know what is right or good in a given situation

for ourselves and for those with whom we share common culture, space, and resources?

Students appeal to early teaching and childhood experience as their moral grounding. Their values are products of their childhood development, similar to their preferred foods. If that is true, and we do acquire our values from parents and teachers, how is it we claim to be autonomous free moral agents? Do our moral values change in the same way our culinary delights do by trying other options? Perhaps talking about what we think, why we think it, and listening to what others think and their reasoning, is a good beginning place for ethics education in any discipline.

In teaching across disciplines it is useful to be vocabulary sensitive because every discipline has its favored jargon. Students find it difficult to believe that anyone would actually lose sleep by having failed to maximize happiness. Articles from the bioethics literature inevitably send students for the online dictionary. Simplifying without diluting the substantive claims of the moral theorists is necessary if we want students to believe that ethics and moral actions are for everyone. If misconduct is to be overcome, it is important that people without advanced degrees in philosophy can participate in the discussion.

Smart students can remember technical terms, memorize mantras, solve complex theoretical problems but that does not portend a working knowledge or willingness to apply the theoretical when the practical situation takes place and they are the moral actor. Students are aware of ethical dilemmas from their own lived experience. They have had to decide to tell the truth or not when the answer they give may bring punishment on themselves or others. They have decided to give or receive unauthorized aid on an exam. They have decided whether to help someone in need at some cost to themselves. Telling the truth, not stealing, are common value choices that are not the exclusive purview of research or medical scientists. Students have a personal ethical code that has emerged from experience, education, and human relationships are still forming. Anyone who is intellectually honest does not think the same thing for four score and ten years. Students may not have a philosophical background that will allow them to quote Plato or a contemporary bioethicist but when they see a virtuous leader in their field of chosen pursuit, they know it. Students are generally unaware of the variety of dilemmas they could face in their scientific careers, therefore a course in Science and Ethics should strive to increase awareness of potential dilemmas and offer an ethical toolkit for the journey.

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## The Principle of Autonomy, and decision-making differences between American and Chinese Cultures

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I have researched the problem about how to practice the Principle of Autonomy for a patient or old person who loses decision-making capacity in China and the USA. What is the difference?

In the United States, often a surrogate from family members makes decisions for a patient who has lost decision-making capacity. In some states the law would like to find the evidence of the patient's past wishes and 'advance directive'. Thus ultimately, this is not a family decision, or even family autonomy. This 'advance directive' of a patient's wishes is important for practicing individual autonomy, and individual autonomy is not only protected by American law but also is recognized by the American culture of making 'advance directives'.

The family, in Chinese culture, functions as a whole to provide consent for significant medical and surgical interventions when a patient has lost decision-making capacity. Older people, including the current generation, do not think it is necessary to give a wish or 'advance directives' before they lose decision-making capacity. One important reason is the culture of Confucian family autonomy. The older people, including the patient, need not to make an 'advance directive', because the family makes the medical decision instead, based on the long Chinese tradition.

Because of that the principle of autonomy could not simply be imported into 'already existing' Chinese cultural systems. The different cultures cause the difference in the relative importance of autonomy between the USA and China. It seems that the family autonomy in China cannot be substituted by the western autonomy. However, in China this can better be done by formulating more individual-oriented laws and policies, such as those that empower the patient to

establish a written 'advance directive' for the family members and physicians to follow regarding surrogate decision making.

The principle of autonomy and the nature of autonomy has long been a matter of philosophical debate. Concerning the Chinese family autonomy and American individual autonomy in decision-making differences, this topic is about how Chinese bioethics applied the principle of autonomy within Chinese culture. What makes a decision autonomous? Who (or what) is capable of deciding and acting autonomously? To what extent should individual autonomy be valued? These questions are significant because autonomy is considered to be a precondition for moral agency in bioethics. Especially this conception of autonomy has important implications for personal responsibility and the relationship between the individual, family and society.

In USA, the utilitarian and the Kantian perspectives on these questions each depend upon particular assumptions about how we make decisions. According to the utilitarian and the Kantian perspectives, autonomy can be considered as the right to be free to self-govern, and the person is capable of, and actually exercising, self-governance. Even when the person is a patient, she is still thought of as an autonomous person.

From the Chinese history and reflecting on modern Chinese contemporary society's morals, Confucianism is the main valuable morality. It permeates into the life of the Chinese. One Confucian thought is to view individuals relationally. Individuals are not thought of as existing independently or being separate from any other being of family members. The family members can act as a whole to make decisions for the patient. This can be called family autonomy. Before my research on this issue, in my mind, I thought a person's relationship with family would be the same in the USA and in China. Based on a philosophy of relationship, people in the USA also have a family, and they should be related with other family members. However, as we know, American bioethics thinks the principle of Patient Autonomy is very important. I needed to research how American patients relate with their family and can practice individual autonomy during decision making. I needed to determine what are the differences with what some Chinese bioethicists termed 'family autonomy' in China.

From my early research, I learned that In the United States the family is involved to make surrogate decisions for a family member who has lost decision-making capabilities. The concepts of autonomy, and surrogate decision makers, are sometimes interrelated. For example, it is worthless to persons who have the right to autonomy, but who have lost their decision-making capabilities, to be placed in situations where they are expected to exercise their autonomy. The practice of having an established order was done for surrogate decision makers, such as the spouse, children, and then parents. It reflects the acknowledgment that the family as a social reality cannot be reduced to a stereotype of the appropriate order of default decision makers (1).

Some surveys in USA found respondents agreed that elderly persons should keep responsibility and authority for making their own decisions for as long as possible. When the person became incapacitated, then decisions would be made by their spouse (if living and able) and children. Allowing elderly persons to keep making decisions, when they are able, is an obvious kind of respect. Respondents said they believed that the family also would be the best and most trusted source to make decisions when their relative was unable to do so. This authority would not constitute disrespect to the incapacitated person.

Although the respondents said they wanted their family and children to be involved in the discussion of advance directives

and care plans, they all wanted, if possible, to have "the last word." They would consider using some kind of external agent, like a person with power of attorney, or a court, but only temporarily when a potentially very difficult decision had to be made, the family were not available, and they could not speak for themselves. However, ultimately they all said they believed that their autonomous decisions should prevail whenever possible, and that this would also preserve their dignity (2).

From my research, it seems that surrogate decision making in the USA tends to be family-oriented. It generally turns first to family members to function as surrogate decision makers for a patient who has lost decision-making capabilities. However, the important point is that some states' laws would find the evidence to support the patient's last wishes and "advice directives," so that decision making is not a family decision or about family autonomy. The family member who acts as a surrogate decision maker is also likely to be a reliable historian of the patient's wishes. This "advice directive" and the patient's wishes are very important for the practice of individual autonomy. Individual autonomy not only is protected by American law but also is a realization of the American culture of making an "advice directive".

Ideally, most American agreed that elderly patients should make their own treatment choices for as long as possible, including the authority to make their own advance directives, but some elderly persons were reluctant to appoint a power of attorney, believing it would mean losing control of their own lives. But only when the elderly could not make competent decisions should the family, guardian, or power of attorney have the authority to act. They saw no role for government, or any other external agent to be involved in this process (3).

In US culture, some family practices are based on a libertarian philosophy. Libertarians regard the family as the creation of its members, or guided by overriding concerns for liberty and equality. They have a view of limited family responsibility and autonomy. These families endorse individual, not family, decision making for medical treatment. This view also favors individual autonomy regarding confidentiality. It requires that adolescents can make their own healthcare decisions. This is despite the evidence that adolescents do not usually have the capabilities of decision-makers who have come of age (4).

This Libertarian philosophy gives individuals control of their place in society. For example, in the USA, there are rules that the family member cannot see the patient's doctor, if the patient has not agreed to it. As a result, physicians are taught to help patients to maintain their decision-making capabilities to choose, and without the influence of family members. For instance, the spouse and children are asked to leave the patient alone with the doctor. The physician then asks the patient whether the patient wants to have all discussions in the absence of family and held in confidentiality from all others. Also, the patient's information cannot be disclosed to family members. (5) With this kind autonomy there are problems. This individual-oriented philosophy can hurt the patient, and damage one's dependence on other family members and society. (6)

Professor Tom Beauchamp said in the Sixth Edition of *Principles of Biomedical Ethics*, concerning the issue of decision making for older persons, like in the USA, the family needs to respect the autonomy of the family members who are patients, and respect their rights to make medical decisions. It is seems worthwhile to protect this autonomy of family members who are patients. But he also points out that respect for autonomy is not an excessively individualistic, absolutistic, or an overriding notion that emphasizes individual rights to the neglect or exclusion of social responsibilities. The

principle of respect for autonomy does not by itself determine what, on balance, a person ought to be free to know or do or as to what counts as a valid justification for constraining autonomy (7).

In the culture of USA, another difference with the culture of China is that when most persons are older, they like to live in an independent living facility. One elderly American in an independent living facility commented, *"You feel like you are independent because you are paying your rent and everything, and you can lock your door and nobody bothers you . . . When you lose your independence, you lose everything including dignity."* (8) This view is very different than the views of older Chinese.

Concerning decision making for American people, the term "dignity" evoked several definitions, including: "individuality," "sense of self and life control," and "respect." All thought it is very important for individuality to be maintained. But most older Chinese like to live dependently with family, they never think to lose dignity because children should have filial obligation to them following Confucianism. (9)

A case study made in Houston TX, USA, about long term care (LTC) options in the USA, is a good example of how differently elderly persons think about autonomy and decision making compared to elderly persons in China. This study showed, on the one hand, that the most preferred option was of keeping elderly persons in caring and loving home situations, either their own or their families. Personal choice and independence were emphasized by elderly persons.

The use of the principle of autonomy and the process of decision-making are differences in the American and Chinese Cultures. China maintains a fluid approach that reflects a wide range of possible determinations of family, usually by an important person of the family who is the family's representative to make the decision. The family, in Chinese culture, functions as a whole to provide consent for significant medical and surgical interventions when a patient has lost decision-making capacities. This can be called family autonomy. Even young Chinese people, do not usually think it is necessary to give a list wish or "advice directive" before they lose decision-making capabilities. A reason to cause the loss of patient autonomy or "advice directive" and other difference in China is the cultural background of Confucianism. Competing views of the family have important implications for research on the topic.

The Confucians traditional family is an ontological-metaphysical account of the family, which appreciates the family as a normative social reality that, as far as possible, should be realized by particular families. This account brings with it preexisting roles for husbands and wives, fathers, mothers, and children. The Confucians traditional family tends to be multi-generational, looking back with respect and support to previous generations. It regards the family as a normative socio-biological unit, it supports the autonomy and integrity of the family. This is why the Chinese family endorses family-based decision making for patient, and the Chinese have no views to make "the last word", when they are in healthy, and the family members and physicians cannot find the evidence about the patient' past wishes and "advice directive" (10).

In Confucian society, close relatives are not merely blood kin or socially supportive, they sustain an ontological element of one's very being. In order not to be one sided and incomplete, one's decisions must be made together with them (11). From the Confucian view, humans have morally significant social organization, such as family, community and state. As a center of relations, a Confucian person must achieve harmonious cooperation with other human persons in these social institutions.

On the one hand, Confucians think that children have a filial obligation to their parents, because children are taken care of by parents, and parents pay more time and money to nurturing children in China, this is the reason why the older who lives dependently with children does not feel losing dignity. In the USA, I can see some of children leave parents around 18 years old, and the parents have limited responsibility to them, the children have a limited duty to take care of the parents, this make the family relationship looser, and the relative' relationship also is looser than in Chinese families. In China, the entire family must take care of a sick family member, including sustaining the burden of discussing treatment options with the physician and making ordinary therapeutic decisions for the patient (12).

As an American said, we know what they do in China, they're very good about taking care of their parents. I know that's a very outstanding trait that they have. It is not so much that way with modern America. It depends on the individual, but as a whole people is not as family oriented to taking care of their parents as they are in the Orient. But we all have that responsibility, I think, and we should have it, to take care and make sure that our parents are taken care of.

Nonetheless, family medical co-decision making can promote the Confucian values of family, family responsibility, and the well-being of individuals. Following the long history of Asia, traditional Confucianism and family decision making will not be changed in the near future.

But Chinese also need to pay attention to a problem relating to family autonomy. For example, According to Confucian customs, the Chinese usually have the physician to explain the patient's condition to family members first. Also, cancer patients are informed only after their family members have agreed on what the physician can tell the patient. In special health care situations, families make decisions for the patient without the participation of the patient (13) During this process, if the children try to hurt the sick parents, or do not make decisions with physician together, family autonomy can lead to abuses. For that, special precautions and protective rules should be established.

We need to make sure that in the Confucian model of family decision making, it can serve as the first bulwark in protecting vulnerable patients (14). We need to make sure that when a family's decision is completely in disagreement with the physician's professional judgment about the medical best interests of the patient, the physician can communicate directly with the patient.

Currently, the patient-physician relationship is not in balance in China. Some physicians are afraid that the patient's family will sue or hurt them, they have to follow the family's decision, even though the doctor may want to try to serve the needs of the patient. Therefore, in a Confucian society, the medical professional should insist on protecting their moral integrity, and the Chinese family should recognize these medical limits.

This model of medical decision making is not unique to Chinese culture, but it is also advocated in some eastern countries. However, there are broad spectrums of views in America that address the potential obligations of children toward their parents. These vary from a very conservative, almost Confucian view, such as those of certain Christians at one end. The libertarian views are at the other end, which emphasize the importance of individual choice for all members of the family.

The principles of autonomy upheld by Western bioethics meets challenges in China. Therefore, Western bioethics could not simply be imported unaltered into traditional Chinese cultural systems. It is not appropriate to just adopt the dominant Western concept of autonomy into the Chinese culture. Indeed, it can also be appropriate to consider and

respect the cultural differences, but there are no "last words" which may have possible negative consequences to patient.

With the principle of the family autonomy, Chinese might think that this can be done by formulating more individual-oriented laws and policies, such as those that empower the patient to establish a written "advance directive" for the family members and physicians to follow regarding surrogate decision making. Currently, a Hong Kong bioethicist is working on the use advance directives in patient decision making.

Contemporary Chinese lives have been corrupted by the libertarian individualist ideology, as young people are becoming increasingly individualistic under the influence of Western culture. In addition, we hope that they will not be so afraid of death that they cannot bring themselves to give the "last word" before they lose their capability of decision making. We also want younger persons to improve their understanding of family autonomy, diseases and medical knowledge. In this way, when younger persons know and understand a disease, such as cancer, and are told of it and what about the cancer patient by the physician, they may not be as emotionally hurt and hope the medical science is unlimited (15).

For some old generation patients who have no knowledge about when a disease is diagnosed as cancer or other serious disease, the physician can tell the family members first. The family can then decide whether or not to tell their relative patient. If they think it is not good to tell their relative patient, they will discuss the treatment possibilities with the physician and make a right decision based on Chinese Culture. This culture can be called harmonious by Confucian view.

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## Concept of "Treatmentalization"

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### Abstract

This paper aims to propose the concept of "Treatmentalization." First, this concept is defined as dependency that occurs when people and society place emphasis not on prevention but on treatment of disease. Second, an example of treatmentalization through treating type 2 diabetes as a lifestyle-related disease is discussed. Finally, the structure and cause of treatmentalization is analyzed.

In the past, main aim of medicine had been to prevent outbreak of infections. Humans were able to avoid many infections with such things as immunization and antibiotic drugs. However, as technologies improved, people increasingly sought to treat other injur and disease. Moreover, extension of medicine has been caused by medicalization and treatmentalization. This paper will consider treatmentalization concurrently with the progression of type2 diabetes as an example, and analyze its structure.

### What is "Treatmentalization"?

"Treatmentalization" was coined by Fujii<sup>3</sup> in 2012 to describe a phenomenon where an individual places great emphasis not on prevention but on treatment of disease. It is the "dependency" on medical treatments in which people assume medical treatment is a remedy for all illnesses ("If I have a disease, I can treat it."), and which is tolerated at individual and/or social level.

Advancement in medical technology often has its benefits. Technological advancements lead to a wider range of treatment options and those which were untreatable now become treatable. When these medical technologies are applied to treatments not only for intractable diseases but also for common diseases, people may increasingly become negligent toward preventing lifestyle-related diseases.

In this regard, it is important to note that the concept of treatmentalization refers to medical practice only. This concept does not include enhancement. Also, the concept of treatmentalization does not deny the importance of appropriate treatments for patients. This paper argues preventive treatments or treatments for congenital, idiopathic, and/or intractable diseases by advanced health care technology are preferable to treatmentalization.

Moreover, treatmentalization is different from medicalization. Medicalization is the process whereby previously non-medical aspects of life come to be seen in medical terms, usually as disorders or illnesses.<sup>4</sup> Medicalization is seen in a wide variety of medical fields such as delivery, psychiatry, death, and aging. In other words, medicalization means expansion of medical treatments' target

<sup>3</sup> The 3<sup>rd</sup> Conference of the Japanese Association for Philosophical and Ethical Researches in Medicine (Kyushu) (8 September 2012) and the 6th UNESCO-Kumamoto University Bioethics Roundtable (8–10 December 2012)

<sup>4</sup> Deviance, Medicalization of PJ McGann and Peter Conrad [http://www.sociologyencyclopedia.com/public/tocnode?id=g9781405124331\\_yr2012\\_chunk\\_g978140512433110\\_ss2-3](http://www.sociologyencyclopedia.com/public/tocnode?id=g9781405124331_yr2012_chunk_g978140512433110_ss2-3)

domains. Treatmentalization therefore might lead people to seek medical treatments at a later time than necessary.

### **Type 2 Diabetes as an example**

Diabetes is a complex group of diseases with a wide variety of causes. People with diabetes have high blood glucose levels. Type 1 diabetes is usually first diagnosed in children, teenagers, and young adults. In this type of diabetes, the beta cells of the pancreas no longer make insulin because the body's immune system has attacked and destroyed them. Type 2 diabetes is the most common type of diabetes. Type 2 diabetes is also associated with excess weight, physical inactivity, family history of diabetes, previous history of gestational diabetes, and certain ethnicities.

Type 2 diabetes usually begins with insulin resistance and is a condition linked to excess weight because muscle, liver, and fat cells do not use insulin properly. As a result, more insulin is needed to help glucose enter cells to be used for energy. At first, pancreas is able to respond to added demand of producing more insulin. However after a while, pancreas loses its ability to produce enough insulin, and blood glucose levels rises.<sup>5</sup>

Progressive stages of diabetes are as follows. When fasting blood glucose exceeds 100 mg/dl, and HbA1c (glycohemoglobin) exceeds 5.6%, it is the beginning of the pre-diabetes stage. When fasting blood glucose level is 126 mg/dl or greater, and HbA1c is 6.5% or greater, it is diagnosed as diabetes. In addition, diabetes progresses into more severe diseases such as cerebral stroke or cardiac infraction (based on arteriosclerosis of great arteries), neuropathy, retinopathy, and/or nephropathy (based on microangiopathy) without proper treatments.

There are approximately 4 treatment stages for diabetes.

- (1) For normal condition, lifestyle improvement is important.
- (2) For pre-diabetes stage, early detection and early treatment are needed. This is called secondary prevention.
- (3) In early stages, internal control such as drugs is needed.
- (4) In the complication stage, symptomatic therapy (surgical operation, dialysis, kidney transplantation) and rehabilitation are needed to maintain patient's life and his/her quality of life respectively. If people maintain good lifestyle, diabetes can be prevented. Also, if patients are able to control their blood pressure at an early stage, they can prevent further complications.

Improvements in techniques as well as social circumstances (law, opinion, system) for organ transplantation will lead to an increase in the number of transplantations for congenital/idiopathic diseases. Additionally, the number of renal transplantations for terminal renal failure (most of them are diabetic nephropathy) will increase as well. At that time, some diabetes patients may believe organ transplantation would be an answer to diabetes, in other words, "If I fail to control my blood glucose level, I can receive renal transplantation to treat it." That is treatmentalization.

Furthermore, let us consider about improvement in regenerative medicine. Radical care for some types of congenital/idiopathic diseases will become possible through advancement of regenerative medicine. As treatment for every disease, injury, and disability would become possible and successful, the quality of treatments would also improve. Improvements in regenerative medicine therefore will in the future resolve the issues surrounding non-autologous organ transplantation such as brain death criteria and conflicts with do-no-harm principle. However, some people may believe

regenerative medicine to be a miracle cure for everything ("If I have a disease or injury, I can depend on regenerative medicine to recover."). This also is an example of treatmentalization.

The same might occur in other medical treatment domains. If new treatment technologies are applied to the population at large as a standard treatment, there are two possible outcomes. In other words, on one hand, health disparity may be resolved while on the other hand treatmentalization will be promoted. If medical technologies improve, they would be applied to congenital/idiopathic disease. Then, application of medical technology may expand to lifestyle diseases and injury by accidents or infections, in turn diminishing the awareness for preventive care.

### **Structure of Treatmentalization**

What is the relationship between Treatmentalization and other ethical concepts, such as justice and fairness. Application of new medical technology in private practice widens health disparity hence resulting in injustice. Such application as a standard treatment may be able to resolve the health disparity. However, treatmentalization will be promoted.

Who will be responsible for the costs and risks? If a benefit concentration to a limited number of people results from application of new technology, and people who do not benefit from it continue to pay its cost, these situations can be said to be a case of injustice as well. Availability of treatments made possible by new medical technology as well as the number of research institutions capable of utilizing them are limited due to the particularity of those treatments. Does profit-concentration to these limited numbers of companies and universities constitute distributive justice?

What is the relationship between treatmentalization and autonomy? Autonomy has two aspects. First, let's consider treatmentalization in relation to autonomy in the context of Anglo-American Bioethics. Self-determination in clinical trials or medical treatment is important. Thus we need informed consent. People have a right to utilize advanced technology in private practice. Autonomy of research institutions and researchers should also be respected. The second aspect is the relation of treatmentalization to autonomy in the Kantian sense. Under this type Autonomy, people must make a choice based on autonomous personality and universal rule (maxime).

The process by which advanced medical technologies becomes a standard treatment is similar to the process of establishing environmental policies. Standardization procedures of advanced medicine by a government is beyond the framework of personal informed consent. Decisions and relevant acts involved not only affect decision-makers or specific patients but also the population at large. Similar phenomenon arises in an environmental policymaking situation. For example, determination on the Fukushima no.1 nuclear power plant does not affect only Fukushima residents and workers, but also Tokyo residents as recipients of electricity supply, every Japanese resident, as well as all living things. Also, who would be responsible for the cost of standardized treatment just like the cost for environmental issues?

Progress of standardization of advanced medicine might lead to neglecting prevention approaches utilized by public health or internal medicine at individual and social level. That is treatmentalizaion. However, why does treatmentalization occur? I think that this is because Human nature prefers the greater amount of pleasure.

### **Previously healthy person model**

A) Lifestyle based on *Yojo*. \* *Yojo* (養生) is a Japanese term for

<sup>5</sup> National Diabetes Information Clearinghouse (NDIC) <http://diabetes.niddk.nih.gov/dm/pubs/diagnosis/> (2012/12/12 browsed.)

“caring for one’s own health and life.” *Yojo* could range from suffering to moderation to pleasure depending on the individual — Pleasure is 0, 1, or more\*.

B) Intemperance lifestyle 1: Intemperance (pleasure) → accident or sickness (suffering) → premature mortality (no change because agent is absent) — Pleasure is 1 or more.

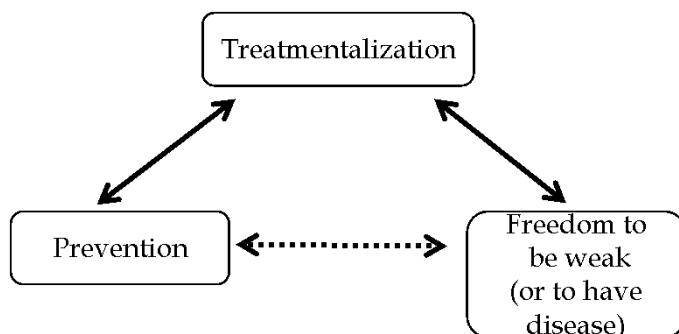
C) Intemperance lifestyle 2: Intemperance (pleasure) → accident or sickness (suffering) → treatment & recovery (pleasure) — Pleasure is equal to 2 or more.

(\*Note: only adding of pleasure, not subtracting for suffering)

Pleasures of congenital disease patients can also be calculated in fundamentally the same way. Though, there are more complicated patterns depending on the combinations of lifestyles. Criteria which determine pleasure and pain depend on the individual. However, people prefer to feel pleasure universally, and most people want to get as much pleasure as possible. Unfortunately, many people repeat intemperance and treatment to achieve more pleasures. This repetitive behavior is in line with treatmentalization.

Repeated oscillation between pleasure and pain causes greater entropy. Entropy maximization in an individual leads to one’s death. Entropy maximization in a population leads to social collapse (e.g. increases in the number of donors and recipients, resources consumption, and the number of people requiring care). That is to say, treatmentalization may bring about loss of individual lives and social lives (social order). This loss is an undesirable result from a biocentric point of view.

There are two possible opposing views of treatmentalization which will be examined in the future: emphasis on prevention and “Freedom to be weak<sup>6</sup>” or freedom to have disease. Treatmentalization and prevention are the concepts which are used in medical situations, while treatmentalization and “Freedom to be weak” (or to have disease) are in that they are relevant to judgments after a person have had medical problems. These three concepts treat individual attitudes toward one’s own health and life, and will be further discussed in the future to analyze structure of treatmentalization, as well as better ways of living.



## Shortage of organ donation resulting from difficulties in the diagnosis of brain death by medical practitioners in Malaysia

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### Abstract

The issues of brain death and organ donation are closely related. Brain death is the irreversible loss of brain function, and from the medical perspective, a person who is brain dead cannot be recovered. The shortage of organs for transplantation is a worldwide problem. One of the reasons contributing to the shortage of organs is the refusal of medical practitioners to diagnose brain death. This paper will highlight four factors why medical practitioners in Malaysia may refuse to diagnose brain death. These factors include: 1) medical practitioners may not accept brain death as true death, 2) a misconception in the diagnosis of brain death, 3) a lack of knowledge about brain death, 4) a lack of responsibility in carrying out professional duties. These four factors will be discussed on the backdrop of ethics as the ethical implications pertaining to brain death diagnosis in Malaysia.

### Introduction

Organ donation is the best method of treatment for patients with end-stage organ failure<sup>7</sup>. Organs such as heart and lungs can only be obtained from brain dead patients. This is because the organs are still fresh from the oxygen supply received through ventilators as the brain dead patients would still be on the life support machine.

Shortage of organ donors is one of the problems faced by many countries, including Malaysia. Malaysia has a low rate of organ donation when the rate of organ donation from deceased donors is among the lowest in the world when compared to other countries. A report from the National Transplant Resource Centre showed that there were only 26 actual donors in 2013<sup>8</sup>. One of the causes for the small number of organ donors is contributed by the low rate of referral of brain dead patients. Referrals are made by doctors who treat patients who have been diagnosed with brain death. Mortality in intensive care units in some hospitals due to brain death is high, but when brain death diagnosis is not done, then the patient would not be on record to be brain dead<sup>9</sup>.

When there is no diagnosis of brain death, then there would not be any referral. As a result, the number of potential

<sup>7</sup> W G Sui et al., “Successful Organ Donation from Brain Dead Donors in a Chinese Organ Transplantation Center.,” *American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 11 (2011), 2247–49 <<http://dx.doi.org/10.1111/j.1600-6143.2011.03694.x>>. p 2247

<sup>8</sup> <http://www.dermaorgan.gov.my/penderma-sebenar-2/>. [accessed 25 August 2014]

<sup>9</sup> Interviewed with Dr. Fadhilah Zowyah Lela Yasmin Binti Mansor (Chief National Transplant Procurement Manager & Donor Coordinator - Malaysia)

<sup>6</sup> Shin'ya Tateiwa (2000) *Freedom to be weak*, Tokyo, Seidosha.

donors would not be as high as it should be. However, it does not mean that if the referral rate is high then the number of donors is also high. At the end of the day, in Malaysia, whether a brain dead patient becomes a donor or not depends on permission given by the next-of-kin (even if the patient is an organ pledger). Nonetheless, high referral rate shows that there is an effort among doctors, especially in the Intensive Care Unit, to diagnose brain death. Some of these patients diagnosed may turn out to be potential donors. The bottom line is if diagnosis of brain death is not done, then the probability of getting a donor is very low.

This paper aims to identify the factors contributing to the shortage of brain death diagnosis. Although Malaysia has accepted the concept of brain death in terms of legislation, religion and practice, it is hypothesized that there are still doctors who do not accept or do not apply the concept of brain death.

## Methodology

### 1) Questionnaires

Questionnaires were distributed to doctors at the University of Malaya Medical Centre (UMMC). A total of 80 respondents were selected consisting of doctors working at four major departments of the hospital namely anaesthesiology, medicine, surgery and emergency medicine. This questionnaire data is collected anonymously to ensure confidentiality. The pilot test was done, and the final version was distributed to respondents. This questionnaire was designed to identify the reasons as to why a low number of medical practitioners in Malaysia diagnose brain death. Many literature written on this matter attributed this to knowledge and attitude of doctors towards brain death. In this survey, a "good knowledge and attitude" can be defined when the doctor do not require any information on brain death, and they can provide information to the families of brain dead patients confidently. This study has been approved by University of Malaya Medical Ethics. The findings were analyzed and the percentages for each answer are presented in the Tables.

### 2) Interview

An interview was also conducted with Dr. Fadhilah Zowyah Lela Yasmin Binti Mansor who is Chief National Transplant Procurement Manager and Donor Coordinator of the National Transplant Resource Centre, Malaysia.

## Results

The table below shows the summary of the results obtained from the study which shows the percentage of the responses given by the doctors to the questions asked. 80 respondents were selected but one of them not give a complete answer. Therefore, only 79 respondents were analysed.

Questions	Yes	No
Do you know what is "brain death"?	100%	0%
Are you involved in the diagnosis of brain death?	37%	63%
Have you ever treated brain dead patients?	76%	24%

The results show that there are many doctors who need additional information regarding brain death. 63.3% of doctors disagreed when asked if they do not need more information on the issue of brain death. If they do not have enough knowledge, it will affect their explanation to the patient's family. That would contribute towards doctors having low confidence when explaining about brain death.

The respondents were also asked whether Malaysia accepted the concept of brain death as death. In total, 54%

answered true, 15% answered false and 30% did not know. While slightly more than half of the respondents answered this question correctly, it is quite alarming that the remaining 46% either answered wrongly or did not know.

On another matter, the majority of the respondents (90%) agreed that doctors should take part in discussions of brain death with the family of brain dead patient.

Questions (%)	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
My knowledge about brain death is sufficient for me to manage brain dead patients.	6.4	31.6	26.6	31.6	3.8
I do not need more information on the issue of brain death.	16.4	63.3	7.6	7.6	5.1
I feel confident that I am able to explain the issue of brain death to the patient's family.	7.6	27.8	27.8	31.7	5.1
Doctors should take part in discussions of brain death with the family of brain dead patient.	6.3	0	3.8	51.9	38
Brain dead patients should become organ donors.	5.1	19	27.8	36.7	11.4
I would like to become an organ donor if I am diagnosed to be brain dead.	8.9	3.8	21.5	33	32.9
Diagnosis of brain death is a way to increase the number of organs for transplant	12.6	19	17.7	34.2	16.5

## Discussion

### 1) Medical practitioners may not accept brain death as a true death

Studies conducted in several countries such as Israel, Italy and Switzerland showed that there are doctors who do not accept brain death as legal death<sup>10</sup>. Approximately 1/5 of doctors from studies conducted in these three countries do not accept brain death as death. Although the concept of brain death is accepted and adopted in many countries, it is still not recognized in countries such as Egypt, Syria and Pakistan.<sup>11,12</sup> Therefore, for this study, a hypothesis was made that Malaysian doctors who graduated from Egypt do not accept the concept of brain death because Egypt does not recognise the concept of brain death as death. Attitudes towards the acceptance of brain death will impact on the organ donation process. Most doctors who do not accept brain death are those who are not involved with the process of organ procurement or who are unfamiliar with the donation process.

Abidin et al in their study done at University of Malaya Medical Centre showed that there are still some doctors who

<sup>10</sup>Jonathan Cohen et al., "Attitude of Health Care Professionals to Brain Death: Influence on the Organ Donation Process.," *Clinical transplantation*, 22 (2008), 211–15 <<http://dx.doi.org/10.1111/j.1399-0012.2007.00776.x>>. p 213

<sup>11</sup>Mohd Rani Jusoh, "Mati Otak: Konsensus Pengamal Perubatan," in *Sempadan Bioteknologi Menurut Perspektif Islam*, ed. by Shaikh Mohd Saifuddeen (Kuala Lumpur: Institut Kefahaman Islam Malaysia (IKIM), 2005), pp. 139–52.

<sup>12</sup>Abdulla A Al-Khader, "The Iranian Transplant Programme: Comment from an Islamic Perspective.," *Nephrol dial transplant*, 17 (2002), 213–15 <<http://www.ncbi.nlm.nih.gov/pubmed/11812868>>.



are unwilling to accept the concept of brain death<sup>13</sup> although the Malaysian Medical Council (MMC) has issued guidelines on the acceptance of brain death in 1996<sup>14</sup>. In this study, however, from the demographic data compiled through the questionnaire, none of the respondents had their medical background from countries which do not accept brain death as legal death. As such, the hypothesis could not be tested.

## 2) A misconception in the diagnosis of brain death

The study conducted at UMMC in 2013 found that only 10.6% of doctors thought only a neurologist could certify brain death<sup>15</sup>. In this study, a similar misconception still occurs, with 24.4% of the respondents answered that doctors involved in the process of organ procurement can diagnosis brain death, and half of them do not indicate that a neurosurgical specialist as a person who can diagnose brain death. This misunderstanding can reduce the number of brain death diagnoses. In Malaysia, it is a legal requirement that doctors involved in certifying brain death consist of two specialists, with at least three years of postgraduate clinical experience who are trained in brain death assessment and diagnosis. They should preferably be anaesthesiologists, physicians, neurologists and neurosurgeons<sup>16</sup>.

## 3) Lack of knowledge about brain death

Lack of knowledge of brain death is a result of little exposure on the concept of brain death among doctors. One of the ways to give a clear understanding is to introduce a formal subject related to brain death and organ donation in the early clinical year of medical training.<sup>17</sup> Lack of knowledge related to brain death will result in discomfort among doctors when explaining brain death to family members of patients. Previous studies showed that the level of understanding of physicians on brain death is poor<sup>18,19</sup>.

This situation is caused by a lack of education and exposure while in medical school. Before this, there are many reports which only assess medical students and physicians' understanding on the issue of organ donation, but these do not focus on basic issues of brain death.<sup>20,21</sup> There are several studies regarding knowledge and attitudes of doctors on the issue of brain death has been carried out in Korea<sup>22</sup>, Pakistan<sup>23</sup>, Egypt<sup>24</sup>, Japan<sup>25</sup> and Poland.<sup>26</sup> The study found

that there are doctors who are not clear about the definition of brain death, and some of them reject the concept of brain death such as those in Egypt.<sup>27</sup>

From the results of this study, 76% of respondents have treated brain dead patients but 63.3% of them still require more information on the issue of brain death. The current knowledge that they have is still not sufficient to manage brain dead patients.

## 4) Lack of responsibility in carrying out professional duties

Based on the interview with Dr. Fadhilah Zowyah Lela Yasmin, it is found that many doctors did not make a diagnosis of brain death to patients who were brought to the Intensive Care Unit (ICU). The patients would be put on life support machine in order to assist the heart and respiratory process. Most of these patients would eventually die when in fact, from the medical perspective, they are already brain dead. Dr. Lela Yasmin is of the view that it would be more ethical for doctors to make a diagnosis of brain death on patients suspected of being brain dead rather than leaving them on the life support machine.

Furthermore, it is responsibility of doctors to explain brain death and organ donation to the patient's family. A study conducted by Abidin et al. showed that the shortage of organs in Malaysia is caused by passive attitude among doctors to identify a suitable organ. Almost two-thirds of respondents had never approached the family of brain-dead patients to explain about organ donation<sup>28</sup>.

Acceptance and application of the concept of brain death as legal death is a major issue in organ donation because the rise of acceptance of brain death can increase the number of organ donors. When the question about diagnosis of brain death is a way to increase the number of organs for transplant were asked, 13% answered strongly disagree, 19% disagree and 18% answered not sure. This may be one of the reasons for the reluctance of doctors to diagnose brain death since they do not view the diagnosis of brain death as a means to increase the number of organ donors. In fact, when the diagnosis of brain death is not implemented, potential donors cannot be identified.

## Suggestions

1) Doctors should be given adequate training and information on brain death which can be started from the beginning of their undergraduate studies. Abidin et al said that they should understand the concept of brain death, and have to be aware of this possibility when treating patients, and be able to recognize and diagnose brain death in the presence of a potential organ donor<sup>29</sup>.

2) Change the attitudes of doctors to be more responsible on the issue of brain death. Doctors should have a more positive attitude towards brain death.

<sup>13</sup> Zada L Zainal Abidin et al., "Are Health Professionals Responsible for the Shortage of Organs from Deceased Donors in Malaysia?," *Transplant international: official journal of the European Society for Organ Transplantation*, 26 (2013), 187–94 <<http://dx.doi.org/10.1111/tri.12019>>, p 6

<sup>14</sup> Mohamed Ismail Merican, "Guidline Of The Malaysia Medical Council", 2006.

<sup>15</sup> Abidin et al.. p. 6.

<sup>16</sup> Mohamed Ismail Merican. p.13.

<sup>17</sup> Cohen et al.. p. 215

<sup>18</sup> S J Youngner et al., "'Brain Death' and Organ Retrieval. A Cross-Sectional Survey of Knowledge and Concepts among Health Professionals.," *JAMA*, 261 (1989), 2205–10 <<http://dx.doi.org/10.1001/jama.261.15.2205>>.

<sup>19</sup> Harrison AM and Botkin JR, "Can Pediatricians Define and Apply the Concept of Brain Death?," *Pediatrics*, 103 (1999), 82.

<sup>20</sup> Elke S Schaeffner et al., "Knowledge and Attitude Regarding Organ Donation among Medical Students and Physicians.," *Transplantation*, 77 (2004), 1714–18 <<http://dx.doi.org/10.1097/00007890-200406150-00015>>.

<sup>21</sup> R C Afonso and others, "Future Doctors and Brain Death: What Is the Prognosis?," *Transplantation proceedings*, 36 (2004), 816–17 <<http://dx.doi.org/10.1016/j.transproceed.2004.03.065>>.

<sup>22</sup> K.O. Jeon et al., "A Study on Knowledge and Attitude toward Brain Death and Organ Retrieval among Health Care Professionals in Korea," *Transplantation Proceedings*, 2012, 859–61 <<http://dx.doi.org/10.1016/j.transproceed.2012.02.019>>.

<sup>23</sup> Sheerani et al..

<sup>24</sup> Sherine Hamdy, "Not Quite Dead: Why Egyptian Doctors Refuse the Diagnosis of Death by Neurological Criteria.," *Theoretical medicine and bioethics*, 34 (2013), 147–60 <<http://dx.doi.org/10.1007/s11017-013-9245-5>>.

<sup>25</sup> Kato Shinzo, "Organ Transplants and Brain-Dead Donors: A Japanese Doctor's Perspective," *Mortality*, 9 (2004), 13–26 <<http://dx.doi.org/10.1080/13576270410001652514>>.

<sup>26</sup> a Kubler et al., "Attitudes to Brain Death and Organ Procurement among University Students and Critical Care Physicians in Poland.," *Transplantation proceedings*, 41 (2009), 1473–76 <<http://dx.doi.org/10.1016/j.transproceed.2009.01.109>>.

<sup>27</sup> Sherine Hamdy, "Not quite dead".

<sup>28</sup> Abidin et al.. p. 2

<sup>29</sup> Abidin et al.. p. 6.

3) Give exposure on brain death to the public through the media and religious bodies. This will help to facilitate doctors to provide information to the patient's family.

### Conclusion

Doctors play an important role in the issue of brain death and organ donation. Understanding and good behavior in the issue of brain death is very important. They should be responsible for each task given. Continuing medical education and increasing awareness are keys in increasing the number of brain death diagnosis.

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## Current debates on "Standard of Care" in Research on Human Subjects in the Developing World

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### Introduction

For sometimes now, medical and bioethics communities have been facing some difficult and divisive issues regarding the ethics of the international research. These issues often get fuel, when the interventional research is conducted on the poor and vulnerable people in the poor developing countries. The common term "Standard of the Care", against which some of new interventions and inventions are tested in the medical research has not been adequately defined. This term is often taken to mean the "best proved treatment" for any of the condition under investigation in any of the trial. The debate regarding what constitutes a reasonable and fair standard of care for subjects in the developing countries, and those who participate in clinical trials has been raised by the critics of the studies on transmission of HIV. Those critics also argued that the placebo controlled trials of the new regimens to prevent the vertical transmission of the HIV were unethical because of the reason that they included the placebo arm rather than "best proven treatment" which is available in the developed countries. While some of the commentators considered criticisms to be unbiased and associated with imperialistic attitudes. Although there was some justified concern that the pressure from US Food and Drug Administration could "dilute" the Declaration of Helsinki, and critics were also confident that whether a trial was ethical could be deduced from text of a declaration. But some

declarations such as Declaration of Helsinki, that governing international research ethics are accepted like the constitutions and needing interpretation. Also assuming what is ethical, goes beyond merely following all the prescriptions and also requires some moral reasoning (1). In this article, I will discuss and comment on various debates on standard of care in human research in the developing world.

### Discussion

Equal standards of medical care during research, reflecting equal respect for the dignity of subjects, could be taken to mean any one or a combination of several requirements. It is arbitrary and not justifiable to select only one of these, for example, which drugs are used to compare the standard of care in developed and developing countries. In the context of some disputed studies on the issue of HIV transmission, the forced emphasis on some "best proven drugs" having greater considerations of whether those drug regimens can be safely applied in the different settings. Also little attention has been paid to fact there were so many differences between the pregnant women in the developing countries, and in countries where "best proven" treatment previously been established. The pregnant women in the developing countries present to the antenatal clinics at much later in the pregnancy than women in original studies; they are often malnourished and anemic, and they often live within some context in which breast feeding has different implications for the newborn infants. Moreover, the advice don't breast feed would then contradict years of the intensive education by WHO (World Health Organization). Also concerning the use of the placebos, the approach has also been simplistic. A placebo arm is legal and justified in any trial requires some careful consideration of the potential benefits and harms in those specific contexts and they cannot be just simply deduced from any general declaration. Of course it is very necessary to acknowledge the fact that many of the placebo trials are often unethical because they are performed largely for the marketing purposes just to show that "me too" drugs, have effects and actions greater than those placebo, and rather than to study that they are better than the existing similar, often cheaper, drugs. Also not only should nothing be done to make it easier to perform such trials, but also each and every effort can be made to reduce and decrease wasting time, and money on the "promotional studies". In these situations where there are some good reasons for the placebo controlled trials, those should be considered on the merits rather than to be precluded by any bluntly designed clause in the declaration. To protect the host communities from exploitation, most of the commentators argue that the efforts to improve the health care in developing countries should never ever involve research that uses and utilizes less than "Worldwide best" methods, and meaning best of methods available anywhere in the world. Most notably, paragraph 29 of the Declaration of Helsinki states: "*The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods*". The debate over the issue what standard of care should be required for the individuals participating in the research trials typically focuses on research conducted in the developing countries by the investigators from the developed countries. This focus makes some sense. Most clinical research is conducted by investigators from developed countries, and most communities lacking access to good health care are located in developing countries. Researchers from the developing countries can also exploit the host communities. Also the communities in developed countries lack access to the best methods available in the world, and increasing the potential of being exploited. Then a complete analysis, should also address the potential for exploitation

and independent of nationality of investigators, and the geographic location of any study (2). When the Helsinki Declaration calls for "*the best proven therapeutic method*" than does it mean [A] "*the best therapy which is available anywhere in world*"? Or does it say [B] "*the standard that is applicable in that country in which drug trial is conducted*"? Helsinki is not very clear about this. But I must say that [1] a detailed and careful analysis of document and also its history tells us that the best therapy standard was intended initially and primarily as the standard of medical practice. This conclusion yields another conclusion: that [2] "*the best proven standard of therapy must necessarily be the standard which prevails in that country in which clinical trial is being carried out.*" In part, interpretations A and B often differ over what we can call the question of relevant reference point. Also emphasizing this disagreement makes it appear as the dispute hinges on question of whose medical practice constitutes relevant medical practice. So, the sides of the debate are divided into the proponents of local standard of care and also the critics who often champion the global standard of care. Framing the debate as the question of relevant reference point, however, effectively obscures a more fundamental source of disagreement. To see this, consider a crucial assumption that lies behind following argument. It is sometimes claimed that (1) because content of the standard of care is often fixed by local reference point and (2) because the prevailing treatment for preventing the maternal-infant HIV transmission in those countries where short-course AZT trials were conducted was no treatment at all, that (3) use of the placebo does not fall below established standard of care. Also it is important to see, however, that in order for (3) to follow from (1) and (2), we have to adopt the local reference point for standard of care (3). The ethics of the placebo-controlled trials to prevent the perinatal transmission of the HIV infection in continents like Asia and Africa have been widely debated. Some critics have argued that it is very unethical to leave the patients untreated when the proven life-saving treatment and therapy is being used in other parts of the world. We note, that conduct of the placebo-controlled trials in any developed country which would be unethical in some other developed country, has evoked some of furor that surrounded HIV perinatal transmission trials. The patients on other hand can choose not to take part in the trials. Reluctance to participate in the trial may be greater when there is some placebo control and the patients are asked to delay and forgo known effective therapy, also a large number of the patients regularly agree to take part in the placebo-controlled trials of new agents. The perceived scientific value of the trial can contribute to this decision. Although care must be taken to ensure that manipulation of such considerations (e.g., by exaggerating scientific importance of trial), it seems very reasonable to allow the potential study participants to balance these benefits against some potential risk of the participation in this trial (4). Some of the observers noted more than decade ago that the research was conducted in the developing countries without the concern for the adherence of international ethical principles regarding human subject research contained in 1947 Nuremberg code and also in the 1964 Declaration of Helsinki. This situation has not improved. For example, two years back, the Food and Drug Administration decided that the research studies submitted to it for the review purpose need no longer be bound by the Declaration of Helsinki and they must follow only the industry-sponsored guidelines for the good clinical practice also outlined by International conference on the Harmonization. What is the legal status of Nuremberg code and Declaration of Helsinki? Are they old outdated ethical rules that the researchers might ignore with impunity? The question remains open, but just as clinical trials attempting to interrupt

mother-to-child transmission of HIV in mid-1990s gave rise to some continuing debate about the global standards of care and also benefit sharing, so another mid-1990s research trial in continental Africa has brought the international research rules back to the center stage (5). In addition to discussing recent debate and concerning international HIV research, also we should focus on whether or not to randomize, as the controlled trials must be conducted for the researchers to learn about intervention's efficacy. The choice of the study design is not between ethically questionable perfect trials that produce the complete knowledge versus the imperfect designs that produce no knowledge. Moreover designs, such as the observational studies, that resolve the certain ethical quandaries are not necessarily free of the other ethical problems. One problem is that these studies can provide only limited guidance for the public health policy. The other issue is of informed consent, which is one of the corner-stones of research ethics. The quality of the informed consent is compromised when the potential patient participants believe, wrongly, that the medical care is contingent on their agreeing to participate in the research. Also it is important to emphasize the potential participants that neither their access to the medical care, nor quality of care they receive, will be affected in any of the respect by their decision. It is sometimes very difficult to clarify this separation of the research from the medical care; the potential participants can be made aware through the effective communication that the decision about the research has no implications for their medical interests. Some more challenging situation occurs when the potential participants rightly believe that the medical care is contingent on their agreeing to enroll in the research (6).

### Conclusion

In conclusion it is stated that every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subjects or to others. Following the fundamental principles of bioethics may help to reduce ethical issues while conducting the clinical trials in resource poor countries. The issues of doing research in the developing countries remains a worry and it need to be focused and debated. We have to sort out ethical problems while conducting any research study. The researchers following the ethical rules might not been able to solve all issues, but the situation might improve by the time if we try it sincerely.

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## Deficiencies in Japan's Medical Ethics Review System

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### Abstract

A major factor in many cases of medical malpractice is the failure of doctor-patient communication. Independent third-party organizations such as the HEC (Hospital Ethics Committees) and the Clinical Ethics Consultation (CEC) are designed to address this problem in the United States and Canada. However, in Japan, open public access to similar patient advocacy groups is less widespread. This deficiency may be contributing to instances of illicit medical practices in Japan and posing as a significant impediment to the realization of "patient-centered health care." Illicit activities such as casually tampering with medical records in order to conceal incidents of medical malpractice occur frequently in Japan, as illustrated by several cases discussed in this paper. The fact that investigations are conducted only after a serious incident occurs reflects the inadequacy of existing ethical safeguards.

**Key words:** medical malpractice, hospital ethics committee, clinical ethics consultation, informed consent, neutral institution.

### Introduction

Actions involving communication between medical professionals and patients, including informed consent (IC), are a frequent cause of problems between medical professionals and patients in modern healthcare. These problems arise from the increasing complexity of healthcare decision-making amidst rapid advancements in medical technologies, a wider range of treatment options, and transformations in social structures. Therefore, the availability of neutral third parties to investigate whether sufficient ethical consideration has occurred in decisions on treatment plans is an important issue. This paper highlights the current status of third-party ethics committees in Japan, where illicit activities such as tampering with medical records continue to occur with surprising frequency.

### The current state and issues of ethics committees and clinical ethics consultations in Japan

Since the 2003 amendment to the Enforcement Regulations of the Medical Service Law, which governs hospitals and research facilities in Japan, advanced treatment hospitals and clinical training hospitals have been required to "provide patient consultation services." This provision has led to the establishment of patient consultation desks at all university hospitals and all so-called "large" hospitals (i.e., those with at least 400 beds). Ethics committees (ECs) began reviewing cases from clinical settings, and hospital ethics committees (HECs)<sup>30</sup> designed to address ethical issues in clinical practice were also formed. HECs in the western countries are composed of physicians, nurses, medical social workers,

<sup>30</sup>Chris Hackler and D. Micah Hester, "What Should an HEC Look and Act Like?" in D. Micah Hester (ed.), *Ethics by Committee: A Textbook on Consultation, Organization, and Education for Hospital Ethics Committees* (Maryland, Rowman & Littlefield, 2007), 6-12.

lawyers, clergy, other experts, and members of the general public such as patient representatives. HECs have three main roles: (1) to provide ethics training to hospital staff; (2) to create hospital guidelines including a code of ethics and to prevent ethical incidents through reviews; and (3) to review ethical issues regarding individual clinical research and medical practice within the hospital and provide clinical ethics consultations (CECs) to address these issues. The number of hospitals establishing ECs (under various names) increased rapidly after the Japan Council for Quality Health Care (JCQHC) adopted the presence or absence of an EC as a criterion in its hospital evaluations.

However, the actual state of ECs differs considerably from that in the United States, which was intended to serve as a model for Japan. ECs are merely formal committees formed to superficially commit to World Health Organization (WHO) guidelines<sup>31</sup> and JCQHC requirements. In practice, they are often monopolized by medical professionals, corporate lawyers, or university stakeholders.

Furthermore, the HECs intended to address ethical issues are not clearly distinguished from research ethics committees (RECs) designed to oversee traditional clinical research. Similar to the United States, Japan has institutional review boards (IRBs) to supervise the conduct of clinical trials, but Japan's IRBs do not have the same responsibilities as their U.S. counterparts. Rather, a complicated system exists whereby RECs are responsible for work that would generally constitute the scope of IRBs in the United States.

For example, the U.S. IRB system reviews all clinical research in facilities based on statutory regulations. However, IRBs in Japan are responsible generally for ensuring the application of good clinical practice (GCP) in clinical trials that are assessed under the country's Pharmaceutical Affairs Law. Clinical research in Japan, other than clinical trials, is instead reviewed by the REC of each hospital or facility, not by an IRB, and is not subject to such strict statutory regulations or monitoring as in the United States.<sup>32</sup>

These problems can be elucidated by comparing several Japanese studies regarding ECs. For example, in a 1995–1996 study of general hospitals, only 24.3% of hospitals had an EC.<sup>33</sup> This number rapidly increased after the JCQHC added its EC criterion to hospital evaluations since 1995. In a 2006–2007 survey of hospitals certified by the JCQHC, 76.4% of hospitals had an EC.<sup>34</sup> Nevertheless, according to a 2004–2005 survey of clinical training hospitals, only 24.7% of facilities responded that they had a structure in place to offer clinical ethics consultations (CECs), which relate specifically to ethical issues in clinical settings.<sup>35</sup>

This information underscores that Japan's HECs are in place only as a formal measure due to external pressure and that it is difficult for these HECs to respond pragmatically

when serious clinical ethics problems arise in medical settings, because the distinction between HECs and RECs is ambiguous. Because they tend to exist only as formalities, they are less likely to have to cooperate with CECs, which address ethical practice in clinical settings. In other words, HECs and RECs, or IRBs in extreme cases, in Japan are currently lumped together with ECs. Although these bodies function as independent committees under the hospital board, in reality, they are often the same in terms of their members and other factors. According to one survey, many RECs and IRBs at facilities and hospitals serve the same function as HECs.<sup>36</sup>

The cases discussed in this paper underscore that the current situation surrounding ECs in Japan is preventing ethical problems from being addressed in clinical settings or making it impossible to act before situations become serious.

Although still small in number, CECs at some institutions in Japan, such as the Center for Biomedical Ethics and Law,<sup>37</sup> the University of Miyazaki, and its associated hospital,<sup>38</sup> and the Graduate Schools of Kumamoto University,<sup>39</sup> have demonstrated a high level of practice and produced useful research findings. Expansion of CECs into advanced research centers is still awaited.

The lack of corresponding third-party and neutral perspectives is the greatest and most common problem of the EC system in Japan. Further, I will discuss the role of CECs, which address the ethical problems of patients and medical settings from a closer perspective, in a case study offering practical solutions to these problems.

#### The purview of CECs as neutral third parties

CECs were initially established in the United States in the late 1960s and evolved with the rapid increase in HECs in the 1980s. CECs were the consequence of the advancement, development, and spread of medical technologies, which resulted in more complex decisions regarding treatment. Their presence was also due to a growing emphasis, which was influenced by broader human- and civil-rights movements, on "patient-centered healthcare"; this would respect the rights of patients, particularly their right to self-determination, in medical settings.

In an epoch-making event, in 1983 the U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research encouraged the establishment of HECs to evaluate and resolve cases demonstrating ethical problems. HECs existed in more than 60% of U.S. hospitals by 1987, compared with a mere 1% five years earlier.<sup>40</sup> Furthermore, 81% of general hospitals and all hospitals with

<sup>31</sup> The WHO guidelines state that research ethics committees should include at least one individual who is not a scientist and one individual who does not belong to the institution in question. See Sengupta Sohini and Bernard Lo, "The Roles and Experiences of Nonaffiliated and Non-scientist Members of Institutional Review Boards," *Academic Medicine* 78, no. 2 (2003): 212–18.

<sup>32</sup> K. Inaba and N. Nagao, "Functioning Clinical Ethics Committees within Hospitals," *Journal of Nursing Management* 13, no. 4 (2003): 263–64.

<sup>33</sup> A. Akabayashi, "The Functions of Ethics Committees: Roles and Responsibilities," in A. Asai et al. (eds.), *Medical Ethics* (Keiso Shobo, 2002), 277–88.

<sup>34</sup> H. Nakao et al., "The Current Status of Recognition and Solution of Ethical Problems in Hospitals in Japan: From the Nursing Administrators' Point of View," *Journal of the Japan Association for Bioethics* 18, no. 1 (2008): 75–82.

<sup>35</sup> N. Nagao, Y. Takimoto, and A. Akabayashi, "Survey on the Current State of Hospital Ethics Committee Consultations in Japan," *Journal of the Japan Association for Bioethics* 15, no. 1 (2005): 101–6.

<sup>36</sup> Japanese Society of Intensive Care Medicine Ethics Committee, "Survey on the Current Situation of Clinical Ethics at Facilities with which Japanese Society of Intensive Care Medicine Counselors are Affiliated," *Journal of the Japanese Society of Intensive Care Medicine* 20, no. 2 (2013): 307–19.

<sup>37</sup> The University of Tokyo Center for Biomedical Ethics and Law was among the first to raise awareness of HECs and CECs in Japan; it holds educational activities and launches CECs. Y. Takimoto, "Building a Clinical Ethics Consultation System," *Journal of the Japan Hospital Association* 71, no. 3 (2012): 222–23.

<sup>38</sup> At the University of Miyazaki, a clinical ethics division was established at the university hospital, with a "medical ethics committee" set up as a HEC based on clinical ethical guidelines. A team of "clinical ethics coordinators" handles ethics consultations. K. Itai, "Ethics Consultation and End-of-Life Discussion: Through the Implementation of Clinical Ethics Consultation," *Journal of Japanese Scientists* 42, no. 11 (2007): 16–21.

<sup>39</sup> A. Asai, "The Question of Ethics Consultation," *Journal of the Japanese Society of Internal Medicine* 101, no. 10 (2012): 3012–18.

<sup>40</sup> J. E. Fleetwood, R. M. Arnold, and R. J. Baron, "Giving Answers or Raising Questions? The Problematic Role of Institutional Ethics Committees," *Journal of Medical Ethics* 15, no. 3 (1989): 137–42.

at least 400 beds had an HEC by 2002, and CECs spread concurrently to the same extent.<sup>41</sup>

Meanwhile, an initial problem with HECs was identified: the criteria underlying their authority to deal with ethical issues in clinical settings were incomplete. Specifically, there were problems with maintaining their neutrality as a third-party entity coupled with the lack of programs to train people to perform the function of HECs. However, in the late 1980s, CECs broke away from HECs and improved their human resources by implementing professional training programs in clinical ethics at universities and other institutions. CECs currently function as neutral third parties providing professional clinical ethics consultants. Their function is to discuss ethical issues with medical professionals, and they are recognized in many clinical settings as important arbiters.

### **Inappropriate medical practices in Japan caused by inadequate HECs and a lack of CECs**

I will now refer to a case in which the inadequate functioning of HECs and the lack of involvement of CECs has encouraged illicit and unethical medical practices in Japan. In this case, I received a request from a consultant, who was serving as a private CEC and as a hospital chaplain, regarding what appeared to be a case of forged amnion transplant surgery,<sup>42</sup> based on treatment information available in the Ophthalmology Department of Gunma University Hospital.

When I examined the patient's narrative about their disease as provided by the CEC, I noticed some discrepancies in the medical professional's narrative of a conference held with the patient following differences that arose between the patient's understanding and that of the medical professional after surgery. Based on these discrepancies, I asked to look at the hospital's medical records and found that the patient information referral document for the doctor had been forged. This experience confirmed that CECs are effective when ethical issues arise regarding medical professionals in hospital settings.

This case was presented at the 26th Annual Meeting of the Japan Association of Bioethics (October 25, 2014); however, the CEC investigation was still underway at the time and the conference between the parties involved—including the doctor in question—had not yet taken place, so the name of the hospital was withheld.

However, in a CEC meeting on April 4, 2014, the hospital ultimately admitted that the medical information in question was not real, apologized to the patient, and agreed to a settlement between the parties.

Following this incident, on November 14, 2014, the establishment of a third-party investigative committee was announced for investigating advanced laparoscopic procedures conducted between 2011 and 2014 at Gunma University Hospital that had resulted in at least eight deaths.<sup>43</sup> These surgeries were conducted with insufficient IC and preoperative examination, were not covered by health

insurance, and should have been reviewed by the EC under the hospital's bylaws.

These laparoscopy cases had many points in common with the amnion transplant case. For example, the surgeon in the laparoscopy cases obtained insufficient IC from the patients and did not indicate in the medical records that these were advanced procedures not covered by health insurance. The testimonies of the surgeon who "provided an explanation" and the bereaved family who "did not receive an explanation" differed. Furthermore, the medical records did not list the procedure as laparoscopic surgery, but instead as a normal laparotomy, referred to vaguely as "resection of two central segments of the liver." As in the amnion transplant case, the truth about what occurred during surgery could be revealed only from the nursing records.<sup>44</sup> In a press release about the laparoscopy cases, the hospital director commented that "the surgeon was only partially aware of the need to file applications." However, the laparoscopy cases were not the only surgeries conducted with advanced medical procedures and without health insurance in 2013; the amnion transplant case also had these characteristics. Despite this, there has been no evidence of the EC reviewing these cases among the disclosed information.

That Hospital has admitted in its final report is at fault in relation to the death of all eight patients who died after undergoing liver operations using a laparoscopy. Also the Hospital's investigation into a series of deaths of patients following liver surgery by one of its doctors was insufficient, lawyers for bereaved family members said, stressing a criminal charge against the operating surgeon is in the offing.

At a press conference, the group of lawyers said the hospital did not conduct a thorough investigation into the director at its second surgical department and the surgeon in question, and thus failed to uncover the whole picture of how and why the fatal operations were allowed to happen. A group of lawyers was set up by eight legal advisers specializing in medical matters and helping those who fall victim to medical malpractice. The bereaved family members of the patients who died following laparoscopic and open abdominal operations at the hospital have consulted the lawyers. Upon receiving formal requests to examine the cases of two patients, the lawyers investigated them in cooperation with a gastroenterological doctor knowledgeable about laparoscopic surgery at a university hospital in Tokyo. Based on the expert's assessment, the group of lawyers raised several questions over the investigative report compiled by the hospital, saying the hearings with the surgeon and the department's director were insufficient.

Also regarding the 10 patients who died after having open abdominal operations, the hospital announced at a press conference last week that one of them was posthumously confirmed not to have developed cancer, but the surgeon did not tell the patient's family about this and entered false disease information on the patient's death certificate. In addition to lodging a criminal complaint against the surgeon, the lawyers will consider demanding the administrative punishment of having his medical license revoked.<sup>45</sup>

These incidents suggest that hospital bylaws do not function effectively, raising concerns that medical professionals' responsibility to apply to ECs is normally neglected or ignored.

On the other hand, the educational philosophy of Gunma University School of Medicine is "reforming the curriculum under the shared slogans of science (scientific knowledge

<sup>41</sup> H. Sakurai et. al., "The Necessity of Layperson Participation in Ethics Committees: A Framework for Commitment," *Journal of Medicine, Life and Ethics, and Society* 8 (2009): 1–16.

<sup>42</sup> "False Medical Records in Ophthalmology," *Yomiuri Newspaper*, February 8, 2015.

Amnion transplant surgery is a treatment for refractory eye disease in which an amnion (the membrane that envelops the amniotic fluid that nurtures the fetus) is transplanted. Because this is an advanced medical procedure, only 17 facilities (as of 2010) throughout the country could perform this surgery based on provisions by the Ministry of Health, Labour and Welfare.

<sup>43</sup> "Deaths Following Laparoscopic Surgery," *Yomiuri Shimbun*, November 14, 2014, morning edition.

<sup>44</sup> "Inadequacies in the Medical Records of Two of the Eight Patients Who Died," *Yomiuri Shimbun*, January 17, 2015, morning edition.

<sup>45</sup> "Forgery of the death certificate by a doctor." *Yomiuri Shimbun*, March 4, 2015, morning edition.

and skills), ethics (ethical standards and social contribution)<sup>46</sup> and skill (medical and research skills).<sup>47</sup> The university also offers a major in medical philosophy and ethics. The dysfunction of the HEC and the inadequate CEC at Gunma University Hospital are the primary causes of the fact that the outcomes of advanced medical ethics instruction at the university are not reflected in the clinical practice of the hospital. The interim report on the laparoscopy cases conducted by the hospital's accident investigation board<sup>48</sup> shows that the complaints of the patients and their families were not sufficiently addressed. It is quite likely that if the CEC had at least been able to present patient complaints regarding informed consent to the HEC as a neutral third party, some of the incidents could have been prevented.

#### Detailed review of the case study

I will now describe in further detail the amnion transplant case study.

Ms. I is a 47-year-old woman and a devout Christian. She lives with her 90-year-old mother and has no other family. She has very weak eyesight in both eyes due to a congenital disorder. She visited many university hospitals for treatment as a child, but there was no improvement in her condition. Since age seven, she has undergone regular testing at ophthalmology clinic D to stabilize her visual acuity at about 0.05. Ms. I worked at a facility for persons with disabilities while receiving assistance with activities of daily living. However, at age 32, she developed Crohn's disease and was admitted to a local general hospital, Hospital E. Thereafter, her eye symptoms worsened due to complications and she underwent treatment with eye drops and ointment at the ophthalmology department of the same hospital. At age 44, Ms. I developed lung cancer; aggressive therapy was not indicated and there was no hope for a cure; therefore she received only palliative care. Initially, she was given a life expectancy of about three years, but no exacerbation or metastasis of the cancer has been observed as of this writing, so she is still undergoing treatment.

Ms. I wanted to be able to read the Bible, with the aid of a magnifying glass, during her remaining life. Due to severe nystagmus (an abnormal form of eye movement in which the eyeball moves back and forth involuntarily) that made reading characters difficult, she was referred to Gunma University Hospital, which supports amnion transplantation, by Dr. M. at the ophthalmology department of Hospital E. She was admitted to Gunma University Hospital on June 24, 2013 and underwent surgery the following day.

According to Ms. I, her IC on admission contained an explanation that "advanced medical treatment not covered by insurance consisting of 'amnion transplant for intractable eye disease' was scheduled." In light of the previously mentioned laparoscopy cases, this procedure likely required review by the ethics committee; however, the medical records did not state that a review took place. Moreover, Ms. I learned from a female doctor, during the preoperative IC explanation, of a sudden change in the surgeon performing the operation. She became anxious, but she reluctantly consented. Surgery was performed under local anesthetic, so the patient was able to

hear the doctors' conversation. At the start of the surgery, the surgeon, Dr. Y, said, "We should just sew her eyes shut because she can't see anyway," to which the assisting Dr. J replied, "Yes, of course." This shocked the patient. After the surgery, Dr. J told Ms. I, "We performed conjunctival graft surgery because you were not eligible for an amnion transplant." Ms. I, who had not been told of the conjunctival graft surgery in the IC explanation, became worried. She wondered why she had not received an amnion transplant and was hurt by the doctors' heartless words. She did not know what to do because none of the doctors or nurses would listen to her. She explained all this to me in a telephone conversation. I rushed to the hospital at her request and asked for an explanation from the ward nurses, at which point Dr. J came to the hospital room to explain.

I asked Dr. J why Ms. I was only told during the preoperative IC discussion that her surgery at Gunma University Hospital was for an amnion transplant. Dr. J responded, "She should have been told that an amnion transplant might not be possible. That's why we performed conjunctival graft surgery." At that point, Ms. I interjected emotionally, "I have no memory of being told that!"

In an attempt to compare the narratives of Ms. I and Dr. J, I launched a CEC investigation. Initially I believed that the doctors merely had not sufficiently disclosed their intentions to Ms. I in the IC explanation. However, during the course of the investigation, I discovered that a much more serious ethical failure might have occurred. My conversation with Dr. J and Ms. I is reproduced below.

Author: "Dr. J, Ms. I claims that she 'did not hear anything about conjunctival graft surgery,' so may I ask how you explained Ms. I's procedure to her in the preoperative informed consent explanation?"

Dr. J: "I explained it to her properly. Look [showing the medical records in his left hand], here it shows that we explained it to her properly with images and all. Ms. I has even signed her name!"

Author: "I see. Incidentally, was anyone else present when Ms. I received the explanation?"

Dr. J: "It was just the patient."

Ms. I: "It was just me."

At this point I believed that the preoperative IC explanation had been inadequate. However, because the patient was still in the care of Gunma University Hospital, I waited until the patient was transferred to Hospital E the following day to contact the Gunma University Hospital Medical Affairs Division. Following discussions with the parties involved, including the surgeon, I conferred with Ms. I regarding the need for a CEC investigation.

The reason for suspected fraud in the IC explanation was that Dr. J's remarks were clearly contradictory. Ms. I has almost no visual acuity and usually requires a magnifying glass when reading books and other texts. However, she had not brought a magnifying glass to the hospital, so it was unlikely that Dr. J had given explanations with images. Consequently, I suspected that Dr. J was concealing the fact that she had not provided a sufficient IC explanation.

However, the medical records from the day after surgery indicated that Dr. J had not given any preoperative IC explanation at all. Rather, another female doctor had provided the explanation. Due to her poor eyesight, Ms. I had not been able to distinguish her from Dr. J and had not even considered that Dr. J was pretending to have been the one who provided the IC explanation. On the other hand, if Dr. J had not actually provided the informed consent explanation, then it seemed likely that Dr. J's remark that she had explained the procedure with images (to a person who could

<sup>46</sup> Gunma University Graduate School of Medicine, Social Contribution Program, 2012 Graduate School "Public Seminar," <http://www.pref.gunma.jp/contents/000232377.pdf> (last accessed on January 7, 2015).

<sup>47</sup> Gunma University School of Medicine homepage, [http://www.gunma-u.ac.jp/html/section\\_3.html](http://www.gunma-u.ac.jp/html/section_3.html)

<sup>48</sup> Gunma University Hospital, "Laparoscopic Liver Resections, Interim Report," [http://hospital.m\\_y\\_ed.gunma-u.ac.jp/wp-content/uploads/2014/12/fukukuukyou\\_tyuukan\\_houkokusyo..pdf](http://hospital.m_y_ed.gunma-u.ac.jp/wp-content/uploads/2014/12/fukukuukyou_tyuukan_houkokusyo..pdf) (last accessed on January 9, 2015).

not see) was fabricated, and that Ms. I was telling the truth when she said she did not receive an explanation.

Ms. I, who was unconvinced by Dr. J's explanation, complained to her attending physician, Dr. M, at Hospital E, and Dr. M then made inquiries into the content of her surgery at Gunma University Hospital. The medical information referral document sent by Gunma University Hospital included falsified content signed by the surgeon, Dr. Y, claiming that "amnion transplant surgery had been performed for the right eye."

Still suspicious, Dr. M made another inquiry but received no response. Despite feeling dissatisfied, Ms. I was discharged a week later and continued to visit Gunma University Hospital on an outpatient basis. However, she was never examined again by Dr. Y or Dr. J again. On March 18, 2014, Ms. I finished outpatient treatment at Gunma University Hospital and was once again referred to Hospital E. Her medical information referral document at this time stated, "(R) Conjunctival graft surgery (Dr. Y)."

With the patient's consent, I obtained copies of these two different medical information referral documents from Hospital E. Consequently, forgery of medical information by Dr. Y was suspected, and I contacted the Medical Affairs Division of Gunma University Hospital. On April 4, I held a CEC meeting with Ms. I and the female doctor (Dr. K) who had provided the preoperative IC explanation, two staff members from the Medical Affairs Division, and the chief nurse. However, Dr. K's statements in this meeting were also implausible, and after consulting Ms. I, I made a request for the full disclosure of all medical records. The conversation occurred in the following manner:

Author: "You are indeed the person who provided the IC explanation?"

Dr. K: "That is correct."

Author: "On the day of the surgery, the male doctor claimed that he provided an explanation with images."

Dr. K: "That must be Dr. J, who assisted [with the surgery]."

Author: "So Dr. J had not met with Ms. I before the surgery, is that correct?"

Dr. K: "I think so."

Author: "What about the surgeon, Dr. Y?"

Dr. K: "He was out of the country for an overseas training program, so he did not return until the end of October."

Author: "So when would this case be reviewed by the hospital's Ethical Review Board?"

Dr. K: "That would be after Dr. Y returned."

Author: "Incidentally, why did this inaccuracy appear in the medical records?"

Dr. K: "Due to the large number of referrals and their responses that I write every day, I do not know if Dr. Y wrote the records himself, even if he did sign them. It is possible that one of the residents wrote them on his behalf."

Author: "That is strange. When Ms. I went to the trouble of complaining to the doctor who originally referred her due to her dissatisfaction with the surgery, her original doctor should have inquired about this on her behalf. You should also have heard about the problems on the day of the surgery from Dr. J. This is bad conduct toward Ms. I, but she is also a claimant who asked her attending physician at Hospital E to 'inquire into the content of her surgery' following her demand to know 'why she was not given the amnion transplant' she requested from the hospital. Is it normal for Dr. Y to leave responses to such important issues to others? I do not think it likely that a supervising doctor such as Dr. Y would ask others to fill in records on his behalf without properly checking them, assuming that he had residents or subordinates. If you, Dr. K, were to do something like that during your training, wouldn't your supervising doctor get angry?"

Dr. K: "That is true."

### **Medical information obtained later from the disclosed medical records (excerpts from parts related to the case)**

Before surgery: as of April 9, 2013

(According to the medical institution's medical information referral document sent to Gunma University Hospital Department of Ophthalmology by Dr. M of Department of Ophthalmology, Hospital E)

Reason for referral: Request for advanced medical treatment for corneal findings in the right eye.

Name of conditions: Microphthalmia, weak eyesight, nystagmus, (right eye) corneal thinning

Medical history: Congenital corneal disorder present from birth, visits to University Hospitals N and K until age 7 for weak eyesight. No history of surgery.

First visit to Hospital E in 1998, at which point nystagmus was marked and visual acuity was poor (visual acuity at the time of initial examination was 0.03 for the right eye and 0.02 for the left eye).

The patient had developed corneal opacity and partial calcification. The patient experienced epithelial detachment of the center of the right cornea in July 2005 and January 2011, which was treated using eye drops and ointment both times and visibly improved. The current case of epithelial detachment of the center of the right cornea started on March 25, 2013 and the cornea is thinning, so please look into whether this patient is eligible for an amnion transplant.

The disclosed medical records supported Ms. I's above-mentioned narrative. Medical records from June 24 also revealed the confusion at the time of surgery related to the change in surgeon, as claimed by Ms. I. Moreover, a section regarding Ms. I's complaint that she had been told only about the amnion transplant was included in the nursing records from the time of admission. The nurses' assessment was "Note: Amnion is to be transplanted due to the worn state of the cornea." This suggests that the nursing department at least knew that Ms. I had been admitted for "amnion transplant surgery."

Moreover, the surgical records from June 25 state that "Conjunctival graft surgery was performed for limbal stem cell dysfunction in the right eye." However, a note reading, "Right: amnion transplant surgery was performed" remains a few pages into the surgical records sent to Dr. M at Hospital E following his inquiry. When the medical records were once again sent to Hospital E on March 18, 2014, the medical information referral document written by an outpatient physician, Dr. W, ended with "(R) Conjunctival graft (Dr. Y) [sic]." The report by Dr. W was consistent with the surgical records. On the other hand, it was impossible to determine from the medical records whether Ms. I was eligible for amnion transplant surgery. However, it was worrisome that no application was made to the ethics committee for a possible advanced medical procedure not covered by health insurance. On the day of the surgery, the amnion had already been prepared, so if surgery had been performed with this amnion, it would have been an inappropriate surgery performed without review by the ERB and may have been in violation of the hospital's regulations.

Thereafter, Ms. I resumed treatment at Hospital E, but returned to me seeking advice after she received the following verbal harassment from Dr. M during a visit to Hospital E at the end of April: "Why did you request the disclosure of your medical records? Do you intend to sue?! This is not what I wanted!"

A patient has the right to request disclosure of medical records. Furthermore, Ms. I had complained to both hospitals stating her desire "to know the truth. If they were wrong I want



them to apologize. I also don't want any other patients to go through what I went through."

Despite this, the remarks by Dr. M regarding the request for disclosure of medical records may have been the result of pressure placed on the doctor due to the relationship between Gunma University Hospital and Hospital E. As is the case at other hospitals in the region, approximately two-thirds of the full-time doctors working at Hospital E are graduates of Gunma University and the hospital relies on resources from Gunma University Hospital for their specialized outpatient clinic and hospital shifts. This relationship may have caused Dr. M to feel the need to protect his professional colleagues at Gunma University Hospital.

I indicated to Ms. I that I would like to meet with Dr. M and ask him about the intention behind his remarks. However, Ms. I said that she was still receiving treatment from Dr. M and preferred that I not interview him. Therefore, instead this fact was conveyed to Gunma University Hospital and a request was made to show consideration to Hospital E.

Thereafter, on November 4, a CEC meeting was held, involving a total of six people: three hospital staff, Dr. Y, the chief nurse, a staff member from the Medical Affairs Division, and me, with Ms. I and her family in attendance. At the meeting, Dr. Y apologized for placing false information in the medical records, and Ms. I accepted the apology with a request that the hospital not put any other patients through what she had experienced.

#### The need to develop practical HECs and CECs in Japan

As stated earlier, various ethics committees other than IRBs and RECs exist at many university hospitals and other institutions. However, parties affiliated with the institution, including doctors, account for the majority membership of these committees'. In many cases, these committees do not have a single expert on medical ethics, let alone experts in psychology, philosophy and ethics, or pastoral care as in the West. It is, therefore, not surprising that these committees are unable to deal with serious incidents such as the laparoscopy cases. Institutions such as Gunma University Hospital instead establish accident investigation boards formed by third parties to conduct investigations. However, the interim report on the laparoscopy cases states, "*Even if an ethical review system is in place at a hospital, no reviews can be conducted if no applications are made by clinical departments. It must be said that in these incidents, the clinical departments were naïve in their awareness of this necessity. A structure that allows for training and guidance to be provided to all clinical departments should be established by expanding the variance reporting system and providing easily understood ethical review manuals.*" It is difficult to fulfill these recommendations if no ethical review system has been established.

Amidst these serious incidents, hospitals have exhibited a problematic attitude in that, in most cases, improving just two of the stipulated roles of HECs, namely (1) the reporting system and (2) training and guidance using a manual, in a top-down manner is considered sufficient. The attitude underlying this approach could be summarized in the following way: "*If the formats of training and manuals are at least established, the hospital will escape responsibility for any recurring incidents by pushing the responsibility onto the parties in question.*" The dysfunction of HECs in fulfilling their third role, reviewing and dealing with problems related to individual clinical medical practices, should be highlighted and addressed. Furthermore, ethical practices should be ensured from the bottom up by learning from other countries about how CECs can function as an effective safeguard of patient rights.

Given the current circumstances, where there is no bottom-up perspective on clinical ethical problems, if a similar incident occurs in the future, medical professionals are likely to trivialize the problem into individual liabilities and the HEC would serve simply to protect the hospital. If medical professionals do not change this outdated pattern of behavior, they cannot be said to have delivered patient-centered care in any meaningful sense.

In other words, Japanese healthcare today requires the establishment and operation of more practical HECs and CECs. HECs should include expert ethicists, psychologists, philosophers, nurses, allied health professionals such as medical social workers, and members of the general public including patient representatives, as is the case in the Western countries. At the same time, well-managed CECs formed around ethics consultants should properly address ethical problems that arise in clinical settings, thereby contributing to the realization of patient-centered care.

## A Re-examination of Organ Sale and its Challenges

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#### Abstract

There is a global consensus of ethicists, politicians, physicians, and international documents that reject any sort of market in human organs. Indeed, this issue has received much attention in the literature in the past few decades, with the majority of commentators placing a high correlation between the sale of organs and financial exploitation. While this argument may be tenable, this analysis seeks to draw out further implications of organ sale, including the idea of moralistic exploitation and the concept that providing a market in a nonmarket good may crowd out certain morals that we should care about. This article will initially discuss the issue of moralistic exploitation, drawing implications from the 2005 UNESCO Declaration on Bioethics and Human Rights and will conclude with applying Michael Sandel's concept that markets crowd out morals to the issue of organ markets.

**Keywords:** organ sale; UNESCO; Iran; exploitation; commodification

#### 1) Introduction

Organ transplant has become widely practiced worldwide with the advent of certain immunosuppressive pharmaceuticals. With an increase in transplant, a critical shortage of organs for transplant has developed a market in both licit and illicit forms of organ trade. There is a global consensus of ethicists, politicians, and physicians that reject any sort of market in human organs—regulated or otherwise. Indeed, the very possibility of creating such a for-profit market in organs, particularly kidneys, for transplantation ignites in many people feelings of significant moral repugnance. Their primary point of contention is that organ sale is exploitative. That is, citizens of rich countries are often cited as preying on vulnerable populations from poorer states. Thus, the potential for exploitation, which is perceived to always underlie commerce in human organs, is held to trump the possibility of increasing life-saving transplants.<sup>49</sup>

<sup>49</sup> Mark J. Cherry, "Is a Market in Human Organs Necessarily Exploitative?" *Public Affairs Quarterly* 2000; 14 (4): 337.

The vast majority of literature on the matter of organ trade places a high correlation between the sale of organs and financial exploitation. The argument, tenable as it may be, asserts that persons in underdeveloped countries are coerced into selling their organs by the offer of profuse monetary sums and extravagant gifts. Because these arguments have been advanced in scores of articles and international documents, this essay will not delve greatly into this arena. Rather, this essay seeks to draw out further implications of organ sale, most notably, the ideas of moralistic exploitation and the idea, borrowed from Harvard Professor of Government Michael Sandel, that markets crowd out morals. Thus, a central question here is not what forms of commodification ought to be legally restricted but what forms of commodification are morally objectionable. The moral status of a contested commodity should figure as one consideration among others in determining its legal permissibility. This essay holds that that a market in human organs would not be ethically sound for it would be exploitative in manners other than financial, particularly morally. Indeed, great societal harm could be produced from such a legalized system. This article will initially discuss the issue of moralistic exploitation, drawing implications from the 2005 UNESCO Declaration on Bioethics and Human Rights, will then address further arguments in favor of organ sale, including arguments from autonomy and that a limited supply demands a market in organs. Finally, the article will conclude with providing further considerations on markets and the idea that markets tend to crowd out morals.

## 2) Moralistic Exploitation: Improper Commodification

Assessing whether organ sale involves harmful exploitation requires one to take an all things considered judgment. The question is not truly whether or not organ markets have harmful elements, as most market systems have harmful features, but whether the costs considerably outweigh the benefits so that it should not be recognized as an acceptable social practice.<sup>50</sup> For the purposes of this essay, exploitation is defined as the act of treating someone unfairly in order to benefit from their work.<sup>51</sup> Organ sales may be exploitative if one party benefits considerably more from an exchange that only marginally advantages, or even leads to the detriment, of the other.<sup>52</sup> For example, in a Marxist theory of market exploitation, exploiters command considerably more value from an exchange than they bring to the transaction, while for the exploited the opposite is true. Hence, by such definitions, organ vendors are exploited financially if they receive significantly less value from the transaction than the worth of the transplant to the recipient.<sup>53</sup>

It has been well documented that vulnerable populations in resource-poor countries are now a major source of organs for rich patient-tourists who are prepared to travel and have the means to purchase organs.<sup>54</sup> Citizens of high-income countries are driven to developing countries in search of organs.<sup>55</sup> The World Health Organization has estimated that around 10,000 organs are sold on the black market every year. As stated, the compiled data indicates that the organ-exporting countries are primarily developing states, comprised mainly of India, Pakistan, and China, while the major organ-importing countries are the more affluent Australia, Canada,

Israel, Japan, Oman, Saudi Arabia, and the USA.<sup>56</sup> Though the question of financial exploitation is beyond the scope of this article, the question as to whether human organ sale has the potential of being financially exploitative appears to be a settled one.

Aside from warnings of financial exploitation, the acceptability of a market in human organs must also be gauged in terms of moral costs and benefits. Moralistic exploitation is the concept in which purchasers and vendors gain from a transaction, which, even if freely consented to, is fundamentally immoral.<sup>57</sup> The idea that such a trade in human organs may beget moral harm is a proper concern and is need of close inspection. If commercialization of human organs would promote equality and liberty more successfully than alternative policies, then this would tip the burden of proof against those who would forbid such a market. Alternatively, if the market would inappropriately restrain freedom, increase inequality, or discourage responsible behavior, such moral concerns may outweigh potential benefits.<sup>58</sup> The moral harm that will be examined in this section arrives primarily in the form of improper commodification of the body, which leads to concerns of human rights and human dignity.

A market in human organs would bring about numerous human rights concerns. One of the primary aims of the 2005 UNESCO Universal Declaration on Bioethics and Human Rights is "to promote respect for human dignity and protect human rights" in the context of scientific advancement.<sup>59</sup> For this reason, this essay will in large part draw from the 2005 UNESCO Declaration to form its conclusions. The principles within the Declaration were agreed upon by the member states of the United Nations Educational, Scientific, and Cultural Organization, and they are signified as being universally applicable to all men and women regardless of factors such as race, age, religion, socio-economic standing, or geographic locale. Included in this discussion will be the principles of human vulnerability, consent, equality, justice, and equity, and human dignity and human rights.

Article 8 of the 2005 UNESCO Universal Declaration on Bioethics and Human Rights asserts that when applying scientific knowledge and medical practice to individuals, the vulnerability of men and women must be taken into account. That is, individuals and groups of distinct vulnerability should be protected and respected. UNESCO defined vulnerability simply as the susceptibility of being wounded.<sup>60</sup> While noting that various commentators on the matter of organ sale report that vulnerable peoples are susceptible to this practice, the notion of human vulnerability appears to be especially relevant to this topic.

The vulnerable populations include, but are not limited to, the illiterate, impoverished, undocumented immigrants, prisoners, and political or economic refugees. Indeed, those populations in resource-deprived countries are a chief source

<sup>56</sup> Yosuke Shimazono, "The state of the international organ trade: a provisional picture based on integration of available information," *Bulletin of the World Health Organization* 2007; 85(12): 955-962. Accessed December 5, 2014, <http://www.who.int/bulletin/volumes/85/12/06-039370/en/>

<sup>57</sup> Cherry, "Is a Market in Human Organs Necessarily Exploitative?" 339.

<sup>58</sup> Mark J. Cherry, *Kidney for Sale by Owner: Human Organs, Transplantation, and the Market*, (Washington, D.C.: Georgetown University Press, 2005), 83.

<sup>59</sup> Henk ten Have, Michèle Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, Principles, and Application*, (Paris: UNESCO Publishing, 2009), 81.

<sup>60</sup> ten Have and Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights*, 155-64.

<sup>50</sup> Cherry, "Is a Market in Human Organs Necessarily Exploitative?" 339.

<sup>51</sup> Cherry, p. 339.

<sup>52</sup> Cherry, p. 345.

<sup>53</sup> Cherry, pp. 345-46.

<sup>54</sup> Alireza Bagheri and Francis L. Delmonico, "Global Initiatives to Tackle Organ Trafficking and Transplant Tourism," *Medicine Health Care and Philosophy* 2013; 16: 888.

<sup>55</sup> Greenberg, "The Global Organ Trade," 238.

of organs for rich patient-tourists.<sup>61</sup> The notion of human vulnerability should not merely be applied to individuals in underdeveloped lands. It is now widely accepted that vulnerability is universal in scope. That is, at some point in life, all humankind is vulnerable, regardless of social status, intelligence, authority, or economic power.<sup>62</sup> For many, the state of vulnerability is transient or contextual rather than inherent. However, it is to those individuals, groups, or communities for whom vulnerability is not a transient state that attention is particularly important.<sup>63</sup> To be certain, the notion of vulnerability is a criticism of the conventional emphasis on individual autonomy as insufficient, and that attention should be directed towards the conditions for humanity's flourishing.<sup>64</sup> What is more, the principle of respect for human vulnerability should be linked to that of human dignity, which reinforces the notion of the unconditioned value of humankind by demanding their inviolability.<sup>65</sup>

Articles 6 and 7 of the UNESCO Universal Declaration on Bioethics and Human Rights concern consent. For the scope of this discussion, Article 7 is of specific interest for it concerns persons without the capacity to provide an informed consent. Indeed, this notion has been viewed as central to the discussion over the legitimacy of selling human organs in a market-like system.<sup>66</sup> In a market system in which organs are procured from vulnerable populations, the fact that a seller has agreed to sell an organ, and is not physically shackled or threatened to do so, does not equate to making a free, uncoerced autonomous choice. That is, since the constraints within which the option to sell a kidney are unjust, and the victims of that injustice do not, and could not have, consented to that injustice, their choice to sell a kidney appears to be only superficially autonomous.<sup>67</sup> Hence, the market exchange is not necessarily as voluntary as market enthusiasts would suggest, for the vendor is coerced, in effect, by the necessities of their situation.<sup>68</sup> For an impoverished individual who is desperately trying to secure a better life for their family and consents to selling a kidney out of desperation, agreeing to a desperate choice does not provide the ethical protection that the doctrine of consent is intended to provide.<sup>69</sup> Indeed, it would seem that the market has capitalized on individuals' desperation. Let it be clear that this is not arguing that impoverished people are inherently less educated and lack the fundamental level of intelligence needed in order to make an informed decision and give informed consent, as some have suggested this argument states.<sup>70</sup> On the contrary, level of education does not play a central role in the logic of this argument.

The notion of informed consent has been near the forefront of the concerns of medical ethics since at least the Nuremberg trials in 1945-46. The medical community, keenly aware of the atrocities committed by physicians and researchers under the ruthless Nazi regime, has since viewed the protection of a person's autonomous choice as of utmost importance. Informed consent refers to an individual's autonomous authorization of a medical procedure or of involvement in research. This involves more than simple agreement or complying with a proposed medical intervention. Explicit authorization of a medical intervention or research involvement through an act of informed and voluntary consent is essential. This can occur only if the patient or human research subject has gained substantial understanding of the proposed action and are void of substantial control by others.<sup>71</sup>

Thus, a convincing argument can be made that vulnerable persons in dire situations, such as a majority of organ vendors, experiencing blatant coercion by virtue of their circumstances, do not have the capacity to consent voluntarily to certain major, and in the case of selling an organ, arguably unnecessary, medical procedures. This argument from coercion draws on the ideal of consent carried out under fair background conditions. It is not an objection to markets, only to markets that operate against a background of inequality severe enough to create coercive bargaining conditions.<sup>72</sup>

On a surface level, it may seem reasonable that one should be given the virtually unlimited freedom or autonomy to sell an organ if one so chooses. However, in practice such a drastic decision is rarely determined by a thoughtful, rational choice. When faced with an option to sell an organ amidst destitute conditions and a very limited field of other options, the choice becomes somewhat insignificant. That is, vulnerable persons have agreed to something they would not have otherwise, if conditions were considerably less pressing.<sup>73</sup> Hence, the intent of the offer made to the potential organ vendor by the broker or middleman is to elicit behavior that contradicts the individual's ordinary operative goals, and in that sense attempts to use the individual as a mere means, not an end. Indeed, those in an impoverished state should not be prompted by monetary exchange to offer the material resources of their bodies, and to convert their own health into a profitable commodity in the marketplace of human replacement parts.<sup>74</sup>

Philosopher Mark Cherry does not advocate for the position that organ markets are coercive, but rather they may be instances of "peaceable manipulation". He distinguishes between the two terms by asserting that coercive actions place or threaten to place others into a disadvantaged state without justification, and it violates the free choice of others. On the other hand, peaceable manipulative actions are those that place or offer to place others into an advantaged state to which they have no prior entitlement. Nevertheless, the line between what Cherry would consider to be coercive and what he would term peaceable manipulation is difficult to draw. As he readily admits, that which may prima facie appear as peaceable manipulation may under closer scrutiny be shown

<sup>61</sup> Bagheri and Delmonico, "Global Initiatives to Tackle Organ Trafficking and Transplant Tourism," 888.

<sup>62</sup> ten Have and Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights*, 158.

<sup>63</sup> S.A.M. McLean, 108. (global bioethics handbook)

<sup>64</sup> ten Have, Henk. "Vulnerability as the Antidote to Neoliberalism in Bioethics." *Revista Redbioética* 2014; 1 (9): 87-92.

<sup>65</sup> ten Have and Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights*, 161-62.

<sup>66</sup> Herjeet Marway, Sarah-Louise Johnson, and Heather Widdows. "Commodification of Human Tissue." Chap. 104 In *Handbook of Global Bioethics*, edited by Henk A. M. J. ten Have and Bert Gordijn, (Springer Netherlands, 2014), 581.

<sup>67</sup> Paul M. Hughes, "Constraint, Consent, and Well-Being in Human Kidney Sales," *Journal of Medicine and Philosophy* 2009; 34: 616-21.

<sup>68</sup> Michael J. Sandel, "What Money Can't Buy: The Moral Limits of Markets." Lecture, The Tanner Lectures on Human Values, Brasenose College, Oxford, May 11-12, 1998, 94.

<sup>69</sup> Marway, Johnson, and Widdows, "Commodification of Human Tissue," 591.

<sup>70</sup> J. Radcliffe-Richards, A. S. Daar, R.D. Guttman, R. Hoffenberg, I. Kennedy, M. Lock, R.A. Sells, and N. Tilney, "The Case for Allowing Kidney Sales," *The Lancet* 1998; 351: 1950-52.

<sup>71</sup> Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 7th ed. (New York: Oxford University Press, 2013), 120-25.

<sup>72</sup> Michael J. Sandel, "What Money Can't Buy: The Moral Limits of Markets." Lecture, The Tanner Lectures on Human Values, Brasenose College, Oxford, May 11-12, 1998, 94-95.

<sup>73</sup> Debra Budiani-Saberi and Sean Columb, "A Human Rights Approach to Human Trafficking for Organ Removal," *Medicine Health Care and Philosophy* 2013; 16: 900.

<sup>74</sup> George J. Annas, "Law and the Life Sciences: Life, Liberty, and the Pursuit of Organ Sales," *The Hastings Center Report* 14, no. 1 (1984): 23.

to be a hidden form of coercion.<sup>75</sup> Thus, games of semantics and attempting to soften terms to make them more palatable are of no benefit to the discussion.

Article 10 of the 2005 UNESCO Declaration affirms that the equality of all humankind in dignity and rights is to be respected. Further, all humanity is to be treated justly and equitably.<sup>76</sup> It has been generally accepted that all humanity be considered equal in terms of dignity, justice, rights, freedoms, benefits, and opportunities.<sup>77</sup> In applying this principle in the context of the question over whether or not creating a market in human organs is morally exploitative, the conclusion that must be drawn is that all humankind, regardless of socio-economic status, equally deserve that their human dignity, human rights, and fundamental freedoms be fully respected.<sup>78</sup> It is difficult to argue that the potential for harm in such a system is mitigated by financial incentives. It seems reasonable that affixing a market price on human organs, even a hypothetically fair one, exploits the desperation of the poor, turning their suffering into opportunity for capitalization.<sup>79</sup> This would not lead to the equality, justice, and equity that is the aim of this principle.

Cherry has asserted that if one is concerned that the poor will be induced by their poverty to sell their organs, one must also be concerned that removing what the poor may see as an attractive option, itself coercively limits the liberty of the poor autonomously to assess available opportunities to better their lives, thereby engendering inequality related harms.<sup>80</sup> However, Cherry does not address the reasoning that the poor may not be in a position, due to their specific vulnerability and desperation, to assess rightly the implications of such a drastic decision. Further, approving of that which is immoral so that good may potentially come is never sufficient justification, which appears to be very close to Cherry's argument.

Lastly, the concept of human dignity, its relation to the commodification of the human body, and the argument that a market in human organs would be moralistically exploitative will be examined here in detail by appealing to Article 3 of the 2005 UNESCO Declaration. Article 3 affirms that human dignity, human rights, and fundamental freedoms are to be fully respected.<sup>81</sup> Further, it states that the interests and welfare of the individual should have priority over the interest of science or society.<sup>82</sup> Along these lines, it is often held that a market in human organs would improperly turn the human body into a mere commodity, a moralistic exploitation. Undoubtedly, the debate over the commodification of the body is rooted firmly in the necessity to safeguard the bodily dignity and integrity of individuals. Specifically, this applies to the need to safeguard the most vulnerable by treating them justly and equitably. Further, though the principle of autonomy and the concept of informed consent are fundamental in healthcare ethics, certain conceptions fail to provide adequate protection for individuals. The principle of justice, coupled with

the other provisions in the 2005 Declaration, requires that additional precautions be put into place.<sup>83</sup>

Commodification turns persons, or parts of persons, into mere items to be bought and sold on an open market to the highest bidder. Rather than taking human beings to be ends in themselves that should be respected, a broadly Kantian approach, persons are taken as objects to commercialize and given an exchange value.<sup>84</sup> Hence, markets have the tendency of crowding out morals, an idea that will be examined in detail later in this article.<sup>85</sup> This is why it is essential for the commodification of the human body to be an essential topic for all nations to consider. These matters are especially prevailing in underdeveloped nations where people are most willing to use their bodies as a source of profit. Thus, when analyzing the needed course of action by underdeveloped nations, Nancy Scheper-Hughes has rightly advised that there is an urgent demand for the development of new international ethical standards for human transplant surgery due to reports of abuses against the bodies of some of the most socially disadvantaged members of society.<sup>86</sup>

Thus, the corruption of the body into mere parts to be sold appeals not to consent but to the moral importance of the goods at stakes, the ones that are degraded by market valuation and exchange. The argument from corruption is intrinsic in the sense that it cannot be met by altering the background conditions within which market exchanges take place; it applies under conditions of equality and inequality alike.<sup>87</sup> Freedom does not consist in the voluntary exchanges individuals make in a market economy, irrespective of the prevailing background conditions. Those who argue in favor of organ markets believe that the problems of commodification and privatization of public life can be addressed merely by adjusting the background conditions within which markets operate. According to these theorists, there is nothing wrong with commodification that fair terms of social cooperation cannot cure; if only society were organized so that people's choices to buy and sell items were truly voluntary, rather than tainted by unfair bargaining conditions, the objection to commodification would fall away. What that argument misses are the specific dimensions of life that lie beyond consent, in the moral and civic goods that markets do not honor and money cannot buy.<sup>88</sup>

### 3) Addressing Arguments in Favor of Organ Sale

Proponents of an organ market scheme maintain that society has a moral duty to save lives, reduce human suffering, and thereby increase human flourishing when it is in our capacity to do so. The arguments in favor of legally permitting a regulated market in human organs often approach the situation from a pragmatic viewpoint.<sup>89</sup> That is, the central arguments revolve around the premise that a worldwide shortage of organs, combined with an already thriving underworld trafficking scene, necessitates a regulated

<sup>75</sup> Cherry, *Kidney for Sale by Owner: Human Organs, Transplantation, and the Market*, 91-92.

<sup>76</sup> ten Have and Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights*, 174-85.

<sup>77</sup> ten Have and Jean, p. 175.

<sup>78</sup> ten Have and Jean, pp. 180-81.

<sup>79</sup> Nancy Scheper-Hughes, "The Global Traffic in Human Organs," *Current Anthropology* 2000; 41(2): 197.

<sup>80</sup> Cherry, *Kidney for Sale by Owner: Human Organs, Transplantation, and the Market*, 84.

<sup>81</sup> ten Have and Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights*, 91-98.

<sup>82</sup> ten Have and Jean, *The UNESCO Universal Declaration on Bioethics and Human Rights*, 91.

<sup>83</sup> Marway, Johnson, and Widdows, "Commodification of Human Tissue," 581.

<sup>84</sup> Marway, Johnson, and Widdows, p. 582.

<sup>85</sup> Michael J. Sandel, *What Money Can't Buy: The Moral Limits of Markets*. 1st ed. (New York: Farrar, Straus and Giroux, 2012), 93-130.

<sup>86</sup> Nancy Scheper-Hughes, "The Global Traffic in Human Organs," *Current Anthropology*, 41, no. 2 (2000): 191

<sup>87</sup> Michael J. Sandel, "What Money Can't Buy: The Moral Limits of Markets." Lecture, The Tanner Lectures on Human Values, Brasenose College, Oxford, May 11-12, 1998, 95.

<sup>88</sup> Michael J. Sandel, p. 122.

<sup>89</sup> A. H. Barnett, T. Randolph Beard, and David L. Kaserman. "The Medical Community's Opposition to Organ Markets: Ethics or Economics?" *Review of Industrial Organization* 8, no. 6 (1993): 669-78.

market in order to combat the criminal activity and boost supply to ailing patients.<sup>90</sup> Proponents of organ sale have more recourse to consequentialist theories. This section will be devoted to addressing arguments in favor of organ sale and also looking at the practice of organ sale in Iran.

Commonly, proponents of a market in human organs, in order to form their case, utilize the argument that sellers are entitled to exercise autonomy. Vendors, as autonomous agents, have the near unbarred freedom to make choices with their bodies, including the option to sell an organ, such as a kidney.<sup>91</sup> Indeed, the argument from autonomy is a common tool for proponents of a market in organs. If the individual chooses to sell, they personally benefit and the money they receive would improve their life chances.<sup>92</sup> Any conflict between non-maleficence and beneficence is increasingly resolved in favor of the libertarian and consumer-oriented principle that those able to broker or purchase a human organ should not be prohibited from doing so. Indeed, in a market situation with a high demand for organs and relatively low supply, the remuneration to the vendor has the possibility of being quite high, resulting in a win-win situation for both the organ vendor and recipient. In this argument, oftentimes concerns for social justice do not figure into the discussion because bioethical standards and principles have been finely calibrated to mesh with both the needs and wants of a consumer-oriented globalization.<sup>93</sup>

What is more, several prominent physicians, bioethicists, and social scientists have declared that kidney sales ought to be allowed since we cannot improve the state of the impoverished by removing the best option that poverty has left. The noted bioethicist Robert Veatch has recently adopted this stance. His reasoning is that since society will continue to be uncaring and neglectful of the wellbeing of the impoverished, it is categorically wrong to impede the sole measure that would benefit them.<sup>94</sup> Further, although the U.S. does not allow commerce in organs, transplant surgeons and hospitals make handsome profits from the business of organ trade. Even the not-for-profit transplant registries and agencies that procure the organs garner for their employees a middleman's livelihood.<sup>95</sup> A worthy question is why should everyone be making money from this business bar the individual whose organ makes the whole enterprise possible.

However, the wealth of information that has been collected on the trade in human organs completely contradicts the oft-cited claim that sale would enable the poor to climb out of the mire of poverty. Lawrence Cohen, an anthropologist at UC Berkeley, along with another team of researchers from Pennsylvania State University, conducted independent studies of families in Madras, India who had had a member sell a kidney. They both came to the same conclusion: individuals who sell kidneys are generally in debt prior to selling and back in debt afterwards as well. They determined that a decision to sell a kidney had less to do with raising

money toward a current or future goal and more to do with paying off high interest debt to local moneylenders. Cohen goes even further by suggesting that once a particular context becomes known to organ brokers as a prospective source of organs, brokers intensify their searches there and moneylenders increase their pressure for repayment of debts. Thus, selling an organ does not appear to further the autonomy that proponents purport; it leads to a false liberty that does not actually benefit the vendors.<sup>96</sup>

What is more, society properly restricts the liberty of individuals in a number of different manners. Laws prohibiting prostitution, limits on late-term abortion, occupational health and safety guidelines, laws requiring seatbelt usage and the wearing of motorcycle helmets are only the tip of the proverbial iceberg. Even when we permit individuals to risk their lives and health, society often regulates the degree of danger. American Footballers must wear helmets and boxers submit to blood tests for infectious diseases. These can all be viewed as governmental or organizational paternalism. The issue is not whether the state has the power to act paternalistically, for it obviously does, but whether it can justify its actions to the satisfaction of citizens.<sup>97</sup> Cherry reasons that the state's coercion cannot be justified, for he has argued that protecting the poor from a market in human organs only closes a wretched range of options still further. He contends that added to the dreadful troubles of poverty are the moralistic coercions of the state, removing options that the potential vendor may see as the best that they have to improve their lot in life.<sup>98</sup>

A second chief argument for proponents of a commercial market for human organs is couched in the language of supply and demand. This is a pragmatic argument which reasons that the scarcity of the organ market can ethically be addressed by employing market forces. As the argument goes, the burdens of the limited supply of human organs demands an open market system. Deeply embedded in this argument is a rationale based upon pure commercialism, and it holds that there is nothing inherently immoral with fashioning commodities out of the human body. Harvard University Professor of Government Michael Sandel has recognized that part of the appeal of markets is that they do not pass judgment on the preferences they satisfy. Markets do not ask whether some manners of valuing goods are higher or worthier than others. For economists, the only valid question between someone willing to buy a kidney and a consenting adult willing to sell is, "How much?" Markets do not discriminate between admirable preferences and base ones, for each party involved decides for himself or herself the value to place on the things being exchanged.<sup>99</sup>

Moreover, as the argument goes, by increasing the supply of organs, the market mechanism will eventually bring the price of organs down, allowing more people the ability to afford their much-needed transplant.<sup>100</sup> However, as George Annas has stated, an increase in supply is not in itself sufficient justification. If the primary issue is supply, increased efforts to make current methods of procurement more efficient should be exhausted prior to embarking on a radically novel

<sup>90</sup> T. Randolph Beard, John D. Jackson, and David L. Kaserman, "The Failure of U.S. Organ Procurement Policy," *Regulation* (2008): 22-30.

<sup>91</sup> F. Moazam, R. M. Zaman and A.M. Jafarey, "Conversations with Kidney Vendors in Pakistan. An Ethnographic Study," *The Hastings Center Report* 2009; 39(3): 29.

<sup>92</sup> David J. Rothman and Sheila M. Rothman, *Trust Is Not Enough: Bringing Human Rights to Medicine* (New York: New York Review Books, 2006), 26.

<sup>93</sup> Nancy Scheper-Hughes, "The Ends of the Body: Commodity Fetishism and the Global Traffic in Organs," *SAIS Review* 22, no. 1 (2002): 62.

<sup>94</sup> Rothman and Rothman, *Trust Is Not Enough: Bringing Human Rights to Medicine*, 26-27.

<sup>95</sup> Leon Kass, *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics*, 177.

<sup>96</sup> Rothman and Rothman, *Trust Is Not Enough: Bringing Human Rights to Medicine*, 27.

<sup>97</sup> Annas, "Law and the Life Sciences: Life, Liberty, and the Pursuit of Organ Sales," 22.

<sup>98</sup> Cherry, *Kidney for Sale by Owner: Human Organs, Transplantation, and the Market*, 93.

<sup>99</sup> Sandel, *What Money Can't Buy: The Moral Limits of Markets*, 14.

<sup>100</sup> Claire Andre and Manuel Velasquez, "Kidneys for Sale," *Issues in Ethics*, 1, no. 2 (1988), accessed December 3, 2014, <http://www.scu.edu/ethics/publications/iie/v1n2/kidneys.html>.

and controversial course.<sup>101</sup> Society can often fall into thinking that economic efficiency—getting goods and services to those with the greatest willingness and ability to pay for them—defines the common good. Indeed, textbook economic reasoning makes such schemes difficult to resist, for if a buyer and a seller can agree on a price for an organ, the deal presumably makes both parties better off.<sup>102</sup> Yet, as has been discussed, this is often a mistaken notion.

Further, it has been argued above that society does not have the duty to preserve life at any cost, including moral, and by whatever means necessary. It would seem that a society should not adopt practices that would create injustices or violate the rights of individuals. Because governments have the mandate to protect its citizens, allowing such an organ market schema does not lead to this protection. In order to further illustrate this, it is necessary to analyze a context in which organ markets are legal.

In this business of organ trade, it is not a Western nation that is the leader of the free-market world. Iran has the curious distinction of currently being the only country to regulate a market in human organs. Some have argued that certain ethical principles can be modified so that what is forbidden in one context may be permitted in another. If this premise holds true, then the market-style schema of Iran has the prospect of being morally praiseworthy. Indeed, when approaching the issue of exploitation in regards to organ donation, the recurring rhetoric is that it would perhaps be desirable to create an official system that would control and supervise transplants and see to the interests of the organ vendor. However, from the collected data available on such a mechanism in Iran, it would seem that it has been applied in a far from perfect manner.<sup>103</sup>

While Iran has garnered more kidneys for renal transplants since implementing their controlled system of financial remuneration, major issues continue to plague it.<sup>104</sup> Financial incentives have been found to be the driving force in the majority of those who decide to be a non-directed donor, not altruism. A mere two years following their donation, 75% of donors were dissatisfied with their decision. What is more, the majority of those who donated were, at time of donation, living below the Iranian poverty line and 56% used their compensation to repay debts.<sup>105</sup>

Though the removal of the middleman in Iran prevents overt commercialism, this system still does not appear to mitigate other exploitative factors.<sup>106</sup> To begin, as has been widely accepted, payment for organs is ethically objectionable as it commodifies that which should not be commodified—the human body. Even if one does not accept the abovementioned position that bodily commodification is morally reprehensible, the fact that vulnerable populations are being preyed upon by wealthier individuals is incontrovertible exploitation. In Iran's system, the financial transaction is made between recipient and vendor without a middleman, per se. Thus, the recipient must have the financial means to be able to afford the paid transplant. The fact that the majority of

Iran's vendors elected to sell an organ while living below the poverty line in order to repay outstanding debts, forces one to question the rationality of the act. It appears that even in Iran's system, vulnerable persons have agreed to something they would not have otherwise, if conditions were less pressing. Hence, there is little reason to believe that untainted selflessness and altruism are the driving forces behind any such donation system.<sup>107</sup>

To summarize, while Iran has attempted to regulate a market in human organs, it has been far from perfect. The literature attests that the majority of persons who sell an organ are impoverished and do so for financial reasons. What is more, after a period of time these vendors come to regret their decision. Thus, quality of life is not increased. This points to the idea that economics is not a free-standing, value-neutral science. Standard economic models assume that markets are inert, that they do not touch or taint the goods they exchange. Yet, if the buying and selling of particular goods alters their meaning, then the case for markets cannot solely rest on considerations of efficiency. It must also rest on a moral argument about how to value the goods in question.<sup>108</sup>

#### 4) Markets Crowd out Morals

While this article has addressed the relationship between markets in human organs and exploitation, further considerations must be explored. Michael Sandel has maintained that markets can have the tendency of crowding out morals. Buying a kidney does not dissolve the good of the kidney, for it will work regardless of monetary exchange. Arguably, though the good may not be spoiled by monetary exchange, the good is arguably degraded, corrupted, or diminished as a result of the selling.<sup>109</sup> Determining whether human organs should or should not be sold requires having a moral conversation, such as the one presented in this essay.

Standard economic reasoning holds that commodifying a good does not alter its character. In this reasoning, market exchanges increase economic efficiency without intrinsically altering the goods that are exchanged. Using financial incentives to ease the gap between supply and demand for kidneys is merely making use of the market for a specific purpose. Thus, the use of market exchanges is mutually advantageous because it makes both parties better off without causing anyone else to be in a worse state. However, this reasoning only works if one assumes that market relations and the attitudes they foster do not diminish the value of the goods being exchanged, and this assumption is open to doubt. As markets reach into the spheres of life and culture that are traditionally governed by nonmarket norms, the notion that markets do not touch, corrupt, or in any way degrade the goods they exchange becomes increasingly implausible. Yet, financial incentives can backfire by crowding out nonmarket norms.<sup>110</sup> Thus, though Iran may garner more organs with their payment system, this does not mean that offering payment for a certain behavior will always procure more kidneys.

Fred Hirsch, a British economist, has argued that conventional, mainstream economics has overlooked what he has termed the "commercialization effect". This is the effect on the characteristics or makeup of a good or activity when it is supplied exclusively or predominantly on commercial terms rather than on some other basis, such as mutual obligation, altruism, love, or feelings of service. Numerous studies have

<sup>101</sup> Annas, "Law and the Life Sciences: Life, Liberty, and the Pursuit of Organ Sales," 22.

<sup>102</sup> Michael J. Sandel, "If I Ruled the World: Michael Sandel." *Prospect*, October 2012, accessed December 5, 2014, <http://www.prospectmagazine.co.uk/regulars/if-i-ruled-the-world-michael-sandel>.

<sup>103</sup> Ofra Greenberg, "The Global Organ Trade". *Cambridge Quarterly of Healthcare Ethics* 2013; 22: 244.

<sup>104</sup> Rizvi, A. H., A. S. Naqvi, N. M. Zafar, and E. Ahmed. "Regulated Compensated Donation in Pakistan and Iran." *Curr Opin Organ Transplant* 14, no. 2 (Apr 2009): 126.

<sup>105</sup> Rizvi, Naqvi, Zafar, and Ahmed. "Regulated Compensated Donation in Pakistan and Iran," 126.

<sup>106</sup> Rizvi, Naqvi, Zafar, and Ahmed. pp. 126-27.

<sup>107</sup> Rizvi, Naqvi, Zafar, and Ahmed. p. 127.

<sup>108</sup> Sandel, "If I ruled the world: Michael Sandel," *Prospect*, October 2012.

<sup>109</sup> Sandel, *What Money Can't Buy*, pp. 95-96.

<sup>110</sup> Sandel, *What Money Can't Buy*, pp. 113-14.

given support for Hirsch's insight. When people are involved in an activity that they consider to be intrinsically worthwhile, offering them financial incentives may weaken their motivation by reducing or crowding out their intrinsic interest.<sup>111</sup> This may also affect the solidarity of the individuals in the population.

Perhaps the most well known illustration of the commercialization effect is that done on blood donation and sale by the British sociologist Richard Titmuss. Titmuss' 1970 book, *The Gift Relationship*, examines this phenomenon by comparing the system of blood collection in the United Kingdom and that in the United States. In the U.K., unpaid, voluntary donors give all blood for transfusion. In the U.S. at the time of the study, some blood was bought by commercial blood banks from individuals, typically impoverished, as a means of making money. After presenting a wealth of data showing that in both economic and practical terms the British system works better, Titmuss argued in favor of the U.K. system and against treating blood as a commodity to be bought and sold on the free market. In the face of the supposed efficiency of markets, Titmuss concluded that the American system led to chronic shortages, wasted blood, greater costs, and an increased risk of contaminated blood.<sup>112</sup>

Further, Titmuss provided an ethical argument against the commodification of blood that offers an illustration of the fairness and corruption objections to markets. Part of Titmuss' argument was that a market in blood exploits the situation of the poor, which constitutes the fairness argument. Titmuss backed up his claim with data supporting his belief that the commercialization of blood leads to more blood being supplied by the poor, unskilled, and unemployed. Thus, in Titmuss' estimation, there was a redistribution of blood from the poor to the rich.<sup>113</sup> Titmuss' second objection was that turning blood into a mere market commodity erodes the sense of obligation to donate and diminishes altruism, which is the corruption argument. Thus, once people begin to view blood as a routinely bought and sold commodity, they are less likely to feel a moral responsibility to donate it. The practice of buying and selling blood demoralizes the practice of free donation, thus leading to the crowding-out effect of market relations on nonmarket norms. Titmuss even worried that market-driven societies could become so inhospitable to altruism that they could be said to impair the freedom of persons to give. Thus, the crowding-out effect could have the ability of eroding the sense of community within a given population.<sup>114</sup>

While an argument from analogy, taken from Titmuss' findings on the blood supply and applied to markets in organs, cannot be empirical, it may infer similarities and offer caution to those desiring a market in organs. The baser conclusion that is to be drawn from this subsection is that the commercialization effect as detailed by Hirsch and Titmuss may decrease the altruistic donation of organs, as individuals perceive they are merely another commodity to be commercialized and pilfered for the sake of profit. Yet, as Sandel has observed, the characteristics of altruism, solidarity, and generosity are similar to muscles that develop and grow stronger with exercise. One defect of the market-driven society is that it lets these virtues languish. Therefore, Sandel's encouragement is that in order to renew our public life, society needs to exercise these characteristics more strenuously.<sup>115</sup>

## 5) Conclusion

This essay has examined the relationship between the sale of human organs and, primarily, moralistic exploitation. Concerns over human rights and human dignity were at the forefront of this discussion. Further, the two chief arguments in defense of organ sale were examined, as was the current government-sanctioned market in Iran. As the literature demonstrates in Iran, regulated markets have been shown not to benefit the vendor financially in the long run. The concluding section offered further considerations on the unintended effects of markets in human organs and drew from Sandel's argument that markets can have the tendency of crowding out morals.

It remains to be seen whether nations aside from Iran will go forward into this brave new world of organ markets. The debate of organ sales could provide an opportunity to educate the public about organ donation and procurement, and open the broader discussion of social justice and equity in income distribution and access to healthcare.<sup>116</sup> Perhaps more worrisome to our society is not the commodification of our body parts, but rather the coarsening of our sensibilities and attitudes, and the perhaps irreversible effects this may have on the way we come to conceive of ourselves. Many in our society are enthusiastic to expend enormous energy and vast sums of money to preserve and prolong bodily life, but in the process our embodied life is stripped of its gravity and much of its dignity. As Leon Kass has defined it, this is, in a word, progress as tragedy.<sup>117</sup>

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<sup>111</sup> Sandel, *What Money Can't Buy*, p. 120-22.

<sup>112</sup> Sandel, *What Money Can't Buy*, pp. 122-23.

<sup>113</sup> Sandel, *What Money Can't Buy*, p. 123.

<sup>114</sup> Sandel, *What Money Can't Buy*, pp. 123-25.

<sup>115</sup> Sandel, *What Money Can't Buy*, p. 130.

<sup>116</sup> Annas, "Law and the Life Sciences: Life, Liberty, and the Pursuit of Organ Sales," 23.

<sup>117</sup> Leon Kass, *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics*, 196-98.

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