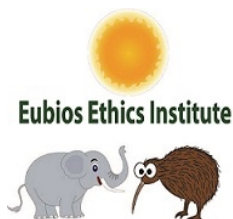


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Editorial: Public Health and Society

This issue starts with a paper highlighting some of the ethical concerns surrounding the 2015 MERS outbreak in Korea by the former President of the Korean Bioethics Association, Prof. Bang-Ook Jun. There are a number of recommendations, including transparency between the public and government in identifying hospitals where cases are being treated, and enhanced and equitable protection for health care workers. Although that outbreak has ended, there are ongoing cases in Saudi Arabia and Jordan with concerns that the increased pilgrimage of persons in September will challenge public health practices.

The next paper examines the Indian court case involving a religious practice of *Santhara* by Jain's and its similarities in the eyes of a Court to suicide which is currently not "legal". Norman K. Swazo explores these links, and we note that there is ongoing legal attention being paid to this distinction. It has some implications for cultural practices that arise in several cultures and in meditative practices that were seen also in the Samurai tradition, and other places. It is surely part of an evolution in the way that we treat end of life. A paper arguing that an Incapacitated Patient has a right to Refusal of Treatment by Hiroko Ishimoto, Sakiko Masaki, Atsushi Asai, examines a hypothetical case from ethical principles.

Three papers from Malaysia are descriptive in methods and include a study on the *halal* certification of medical devices in Malaysia by Nur Farhani Zarmani et al. A nurturing model of ethics and medicinal education at USM is presented by analyzing student diaries as they accompanied practitioners by Nor Azwany Yaacob et al. Angelina Patrick Olesen, Siti Nurani Mohd Nor and Latifah Amin present a Qualitative Study of the Attitudes of Three Selected Groups in Malaysia on ethical implications of Pre-implantation Genetic Diagnosis (PGD), finding generally positive religious and medical attitudes to the practice, and supporting informed consent by parents. Yuanyuan Liu explores through some Chinese cases challenges in researchers use of ethics committees and appropriate informed consent forms.

We look forward to publishing more papers soon, and will be including some from the forthcoming 16th Asian Bioethics Conference, to be held 3-8 November in Manila. EJAIB has signed an agreement with EBSCO to include EJAIB papers in the EBSCO journals service, although all the contents are available on the web through browser searches, this may increase the visibility of the papers through another platform.

- Darryl Macer

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Ethical Concerns Surrounding MERS Outbreak in Korea

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Middle East respiratory syndrome (MERS) is a highly lethal respiratory disease caused by a coronavirus (MERS-CoV).¹ Since the first case of MERS-CoV in Korea was confirmed at 20 May 2015, the numbers of cases seems to have dropped after 17 June 2015. Thirty five patients died and 186 patients have been confirmed, while 16,668 unconfirmed patients were quarantined (as of 10 July 2015), though the introduction of MERS-CoV was started by a single traveler. The Korean outbreak is the largest outside the Arabian Peninsula.

Many authors pointed out several reasons to contribute to this unexpectedly large and complex spread of MERS-CoV in Korea.² First, MERS is comparatively new disease. With the exact mode of transmission and source of MERS coronavirus still unknown, the development of treatment, let alone vaccines, remain a long way off, making prevention all the more important.³ And the relative lack of preparation for such a novel disease resulted in the rapid transmission in healthcare settings and beyond.⁴

Second, MERS-CoV is difficult to diagnose particularly in the early stage of infection. The index patient did not report his recent travel history.⁵ This low index of suspicion caused a delay in the initial diagnosis,⁶ and the important reason for the spread of the virus may be relative unpreparedness for prevention and limited epidemiological expertise.⁷

Third, the conditions and customs of Korean hospitals made the matters worse. Emergency rooms are often crowded and have not adequate isolation and ventilation facilities, and patients on wards often use the family members and non-hospital caregivers to

provide basic care.⁸ The habit of doctor shopping, visiting multiple hospitals seeking care, also facilitated the spread of MERS-CoV.⁹

Other reasons with some ethical concerns contributed this outbreak. The government did not disclose hospital names, so the further transmission of the MER-CoV was unavoidable. The hospital did not supply sufficient protective gear to protect the healthcare workers and increasing numbers were infected as a result of poor infection control measures.¹⁰ Also they even discriminated between regular workers and part-time workers in protection of infection. Lastly, the self-quarantined MER-CoV carriers behaved in out-of-control manner.

Governmental Secrecy over MERS-CoV Information

There has also been concern that government secrecy triggered panic and led to unnecessary disruption.¹¹ The Korean government refused to identify the hospital where the patients visited or were being treated. However, this refusal fueled the rumors: People could not know whether they had been exposed. Patients who should be treated got fear of going to any medical facilities. All the reported cases during the early phase of outbreak were among the medical staff, patients or visitors at several hospitals. The secrecy did not curtail but raised the risk of disease as shown by the Korean case. The first line of an endemic defense must be full and complete transparency between the public, government agencies and nations.¹²

The opposition party accused the government that the refusal to disclose the name of hospitals that treated MERS patients eventually lead to containment failure of the MERS-CoV. The government might apparently fear the announcement would hurt the profits of the hospitals.¹³

The Korean government also tried to downplay concerns about the disease. Worrying negative economic effects, President Park and other governmental leaders urged the public and the

¹ A Zumla, D S Hui, S. Perlman. 2015. www.thelancet.com

² M H Hyun, Y Park. 2015. Re: Why the panic? South Korea's MERS response questioned. *British Medical Journal BMJ* www.bmj.com/content/350/bmj.h3403/rr

³ 2015. MERS-the latest threat to global health security. www.thelancet.com *The Lancet* 385:2324 Published online 13 June 2015.

⁴ C Thomas. 2015. MER-CoV: Where are we now? *Annals Academy of Medicine* 44:155-156.

⁵ World Health Organization. Middle East Respiratory Syndrome (MERS) in the Republic of Korea. http://www.who.int/csr/disease/coronavirus_infections/situation-assessment/update-15-06-2015/en/ Published online 15 June 2015.

⁶ M H Hyun and Y Park. 2015. Re: Why the panic? South Korea's MERS response questioned. www.bmj.com/content/350/bmj.h3403/rr

⁷ A Jack. 2015. Why the panic? South Korea's MERS response questioned. *British Medical Journal BMJ* 2015;350:h3403 Published online 24 June 2015.

⁸ A Jack. 2015. Why the panic? South Korea's MERS response questioned. *British Medical Journal BMJ* 2015;350:h3403 Published online 24 June 2015.

⁹ World Health Organization. Middle East Respiratory Syndrome (MERS) in the Republic of Korea. http://www.who.int/csr/disease/coronavirus_infections/situation-assessment/update-15-06-2015/en/ Published online 15 June 2015.

¹⁰ A Zumla, D S Hui. 2014. Infection control and MERS-CoV in health-care workers. *Lancet* 383:1869-1871. www.thelancet.com Published online 31 May 2014.

¹¹ A Jack. 2015. Why the panic? South Korea's MERS response questioned. *British Medical Journal* 350:h3403. Published online 24 June 2015.

¹² When secrecy kills. <http://www.taipeitimes.com/News/editorials/archives/2015/06/06/2003620020> Published online 6 June 2015 MailOnline. 6 June 2015.

¹³ NPAD accuses government of favoritism to Samsung hospital. <http://www.koreaherald.com/view.php?ud=20150619000970> Published online 19 June 2015

business community to return to normal.¹⁴ The authorities tried to persuade society that MERS is just another seasonal flu, and simple hygiene such as hand washing may effectively prevent this disease. As the extent of human-to-human transmission was unclear, this attitude could mislead people. As the consequences of infection seem to be severe, people should be more prepared to prevent the transmission according to the precautionary principle.¹⁵

Hospital Negligence

The most important thing to manage a viral respiratory infection is the containment of the index patient and probable carriers inside the hospital. In case of the close contact, it was recommended by the U.S. Centers of Disease Control, that the medical staffs, patients and visitors wear a surgical mask, gown and gloves on entering the emergency room and wards. The second edition of the Korean MERS manual, used by 24 May 2015, neglected the above guidelines. Medical staffs staying in the same treatment facilities for symptoms of respiratory infection, or visitors within 1 meter of the patients were only considered as close contacts, and probable carriers without this range were omitted from the quarantine list. In addition to contact precaution, airborne precautions should be applied to reduce contamination in the hospital setting. Medical facilities should apply proper room ventilation rate and the suspected patients should be contained in this proper ventilated room. In fact, Samsung Medical Center has sufficient mechanical ventilation rooms and a separated infirmaries, but it did not contain patients in well-equipped emergency rooms.

As of 26 June 2015, totally 39 medical staff were infected by MERS-CoV. Eight doctors, 15 nurses and 16 workers were included. This high infection ratio indicates a failure of sufficient protective measures for health care workers. The protective gear of Samsung Medical Center staffs had apparently been insufficient. The Ministry of Health and Welfare reinforced the protection measures afterward. While the government recommended Samsung Medical Center to provide D-level protective gear for medical staff, it provided protective equipment called VRE - which leaves the neck and ankles exposed - until 17 June 2015.¹⁶ Another ethical issue that workers in the medical facilities were not treated equally is arising. In early outbreak, hospital orderlies were not provided with masks nor protective clothing. The ninety second

patient, security officer emergency room of Samsung Medical Center was not wearing N95 mask,¹⁷ had been in contact for about ten minutes with the Sixth patient aged 71, dead and confirmed with MERS-CoV infection.¹⁸ After the infection, the Ministry of Labor recommended the hospital to supply masks for outsourced workers.

Also the hospital was accused of a poor probable patients' listing. After close contact with the fourteenth patient, an ambulance worker came into contact with patients and medical staffs for nine days who were having MERS symptom. The hospital omitted the worker from the quarantine list only because he was a non-regular worker.¹⁹

Patient (Carrier) Irresponsibility

Some people did not show willingness to follow the quarantine procedure and in some instance the hospitals did not give clear directions for quarantine. For instance, the son of the third patient, after close contact with his father, then took a flight to Hong Kong to China via Hong Kong despite the onset of symptoms. He was later in isolation with confirmed MERS in Huizhou, Guangdong province, and high-risk close contacts were under surveillance. His trip widened the international pool of people who have to be tracked for possible exposure to the disease.²⁰

Even a Korean doctor couple, after treating a MERS patient, defied self-quarantine and visited Philippines.²¹

The governmental secrecy, Hospital negligence, and probable patients' irresponsibility altogether increased the risk of transmission of the MERS-CoV and those eventually lead to harm to others. The principle of nonmaleficence designates that one should not act in ways to cause harm to others. Particularly, one should avoid harm or even the risk of causing harm. This principle can be violated with or without intention. Even if someone doesn't intend harm to a patient or other person through unnecessary risk, he/she cannot avoid violating this principle. Though the government, hospitals and probable patients in quarantine did not intend harm to other persons, they unknowingly subjected people to unneeded risk and they were supposed to violate this principle.²²

¹⁴ J Kim, J-M Park. Moody's say MER poses risk to South Korean economy, signs outbreak slowing. <http://www.dailymail.co.uk/wires/reuters/article-3129149/Moodys-says-MERS-poses-risk-S-Korean-economy-signs-outbreak-slowing.html> Published online. 18 June 2015.

¹⁵ J W Choi, K H Kim, Y M Cho, S H Kim. 2015. Current epidemiological situation of Middle East respiratory syndrome coronavirus clusters and implications for public health response in South Korea. *Journal of Korean Medical Association* 58: 482-497.

¹⁶ Another samsung doctor contracts MERS. <http://www.koreaherald.com/view.php?ud=20150626000879>

¹⁷ Ministry of Labor recommend "The hospitals must supply masks for subcontracted workers." http://news.khan.co.kr/kh_news/khan_art_view.html?artid=201506121546561&code=940702 Published online. 12 June 2015.

¹⁸ <http://koreatechblog.com/weather/mers-virus-outbreak/>

¹⁹ MERS-stricken Samsung hospital faces crisis. <http://www.koreaherald.com/view.php?ud=20150616001120> Published online 6 June 2015.

²⁰ 2015. MERS-the latest threat to global health security. *www.thelancet.com* The Lancet 385:2324 Published online 13 June 2015.

²¹ L. Abella. South Korean doctors defy MERS self-quarantine, visit Philippines. <http://kickerdaily.com/south-korean-doctors-defy-mers-self-quarantine-visit-philippines/> Posted on 9 June 2015.

²² <http://rhchp.regis.edu/hce/ethicsataglance/Nonmaleficence/Nonmaleficence.pdf>

Research Ethics

The other minor ethical issue of the research ethics can be raised. Recent MERS outbreak in Korea probably put pressure on epidemiologists to accelerate paper publication as fast as they can. Three rapid communications were published in the same copy of *Eurosurveillance*,²³ a medical journal published by ECDC and one regular paper was published in Korean Journal of Medical Association²⁴ already. The race to publish could lead them to ignore research ethics, as we have seen before.²⁵ Two investigators of Gyeonggi Infectious Disease Control Center Epidemic Intelligence Service asked the journal *Eurosurveillance* to retract the epidemiological paper on the South Korean MERS-CoV cases because investigators of Gyeonggi infectious disease control center used the data on 37 MERS-CoV cases at St. Mary Hospital in Pyeongtaek without proper permission of the center and they added names of two complainants who were not informed about the content of that paper.²⁶ So the journal *Eurosurveillance* published a note of concern on the improper authorship and data use.²⁷

Experimental Treatment

Besides these ethical concerns, there can be another ethical issue using unproven treatment directly to the patients. At Samsung Medical Center, two MERS patients were injected with blood plasma from fully recovered patients.²⁸ The plasma therapy was conducted on two MERS patients after obtaining their consent²⁹ to improve the emergency condition where no other treatment was available.³⁰ The clinical basis of

injecting blood plasma on MERS patient is weak, though it was previously used on patients infected by SARS and Ebola.³¹ A phase 2 clinical trial of serum containing antibodies from MERS survivors is being planned.³² Though this convalescent plasma therapy is suggested as the emergency measure for MERS-CoV infected patients,³³ it could raise several questions; how can we analyze danger against safety of that therapy, in what patients' condition can we apply plasma injection therapy, or can we prepare additional guidelines to conduct plasma injection?

Conclusion

The Korean MERS-CoV outbreak was extraordinarily large and complex due to the unpreparedness for this comparatively new disease. MERS outbreak in Korea not only raised the concern over endemic disease but also called attention to several ethical issues such as governmental secrecy, hospitals' negligence, patients' irresponsibility, and researchers' misconduct. The former three altogether were supposed to violate the principle of non-maleficence, and that eventually caused illness and even death to patients. In addition to the proper prevention and treatment measure, we must raise some ethical sensitivity to cope with the risks of this deadly pandemic disease.

Santhara between Law and Morality: India's Dilemma about a Jain Practice

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The Legal Issue

In the year 2006, Mr. Nikhil Soni filed a D.B. Civil Writ Petition (No. 7414), a matter of public interest litigation (*Nikhil Soni v. Union of India & ors.*), filed with reference to Article 226 of the Constitution of India. (High Court, 2015) At issue is the practice of "santhara" (also called "sallekhana") performed by members of the "Shvetambara group" in the Jain

²³ Avian Flu Diary. <http://afludiary.blogspot.kr/2015/06/eurosurveillance-three-mers-rapid.html>

²⁴ J W Choi, K H Kim, Y M Cho, S H Kim. 2015. Current epidemiological situation of Middle East respiratory syndrome coronavirus clusters and implications for public health response in South Korea. *Journal of Korean Medical Association* 58: 482-497.

²⁵ K Kupferschmidt. Research team clash over too-similar MERS papers. <http://news.sciencemag.org/asiapacific/2014/06/research-teams-clash-over-too-similar-mers-papers> Posted online 10 June 2014.

²⁶ Epidemiology investigators and medical doctors struggling over MERS paper published in an international journal. *Chosun Ilbo*. Published online 3 July 2015 (in Korean).

²⁷ H Y Park, E J Lee, Y W Ryu, Y Kim, H Lee, S J Yi. 2015. Epidemiological investigation of MERS-CoV spread in a single hospital in South Korea, May to June 2015. *Eurosurveillance* 2015;20(25):pii=21169. <http://www.eurosurveillance.org/Viewarticle.aspx?Articleid=21169>.

²⁸ South Korea Tried Old Weapon to Fight MERS. *The Wall Street Journal* Published online 17 June 2015.

²⁹ South Korea conducts experimental plasma therapy on MERS patients. <http://www.reuters.com/article/2015/06/16/us-health-mers-southkorea-deaths-idUSKBN0OV2XU20150616> Published online 16 June 2015.

³⁰ South Korean begins experimental MERS plasma trial considers economic stimulus. <http://www.washingtonpost.com/news/to-your-health/wp/2015/06/16/south-korean-officials-go-on-offensive-against-mers-plasma-trial-begins-stimulus-considered/> Published online 16 June 2015

³¹ Y Cheng, R Wong, Y O Y Soo, W S Wong, C K Lee, M H L Ng, K C Wong, C B Leung, G Cheng. 2005. Use of convalescent plasma therapy in SARS patients in Hong Kong. *European Journal Clinical Microbiology & Infectious Disease* 24: 44-46.

³² Too many unknown stymie response to MERS. www.thelancet.com Vol 386:15 Published online 4 July 2015.

³³ Anti-MERS-CoV convalescent plasma therapy <https://clinicaltrials.gov/ct2/show/NCT02190799?term=MERS&rank=4>

religion, *santhara* a matter of “giving up the body,” involving “a fast unto death,” commenced after taking a vow. The Court recognized the respondent definition of ‘*santhara*’ with reference to Jain scriptures, as an action undertaken “to weaken the strength of the body and passion for putting an end to the bodily existence without consciously coveting death by fasting” (italics added). There are conditions for undertaking this vow, i.e., “one is faced with an unavoidable natural calamity, severe drought, old age or an incurable disease,” with a strong recommendation that the matter be discussed “thoroughly and frankly” with a religious preceptor (*guru*).

There is a difference between petitioner and respondents on the question whether Jains believe *santhara* to be a means to *moksha* (denied in argument from respondent). The Court acknowledged that, “Jainism believes in rebirth and so the consequences of our Karmas are dependent upon own good and bad thoughts, words, and deeds.” The goal of *santhara* is intentionally to “purge the soul from karmas” and to “attain salvation in the least possible number of birth and death cycles.” Jainist “metaphysics” understands the body to be one’s “non-soul” (*ajiva*), related to the soul (*jiva*), an individual to direct his/her life so as to be emancipated from this entanglement (a goal called “*atma darshan*”). Jainism assumes an individual to be master of his/her own destiny, in which case it follows as a matter of his/her own rational decision that s/he “follow the best method of leaving the body.” The argument here involves a conditional proposition: *If* and “when the body does not cooperate to help in living meaningfully any more, [*then*] the person should resolve for *Santhara*.”

Petitioner in this case claimed that the practice of *santhara* is a matter of religious thought but should be treated as an action both “illegal and punishable under the law of the land” because (1) a religious practice, however voluntary, “cannot be allowed to violate the right to life of an individual,” and (2) the practice of *santhara* “amounts to ‘suicide’ [defined here as “intentional killing of oneself”], which is a criminal offence” and punishable as such under the penal code. ‘Intention’ here involves an individual’s understanding and anticipation of “the probable consequences of what he is about to do.” The Constitution of India recognizes a right to freedom of religion (Article 25) as a *fundamental right*, even as Article 21 of the Constitution recognizes a citizen’s entitlement “to freedom of conscience and the right freely to profess, practice and propagate religion.” However, the claim from petitioner is that the right to life has precedence, in which case the entitlement to religious belief and associated practice is limited thereby.

The State government adopted a “protectionist” position on grounds of the fundamental right to freedom of religion and objected, *inter alia*, that petitioner failed to substantiate his claims in a way that is required for public interest litigation. It is granted that, only by “interests of public order, morality and health” may the right to religious freedom be limited as a matter of

public law. The Court noted the claim of one respondent that at issue here is a contraposition of Hindu (majority) and Jain (minority in religion and cultural community) religious beliefs and practices, hence “private ends” represented in bad faith as a matter of public interest and the public good. Respondent furthermore cited court judgment (Smt. Gyan vs. State of Punjab, JT 1996(3), SC 339), according to which an individual who is terminally ill and dying may claim a right to die with dignity “as a part of right to live with dignity.”

The court in the cited case opined that such cases do not involve “extinguishing life” but instead “accelerating conclusion of the process of natural death which has already commenced.” However, this is not to be confused with voluntary *active* euthanasia as understood in European and American contexts of the debate about assisted dying. There is some claim here that the Jainist practice of *santhara* may be the same as *passive* euthanasia as understood in the European and American contexts, insofar as withdrawal of life support is permissible in cases of terminal illness. The analogy is that *santhara* is the equivalent of withdrawal of life support. Under the Jain metaphysics, death is a process involving exchange of body, in which case, respondent argues, an individual may claim “a moral right to terminate his life.”

In its decision issued on 10 August 2015, the High Court of Judicature for Rajasthan, India, expressed its supervening question: “whether the practice of *Santhara/Sallekhana* practised by the Shbetambaras group of Jain religion is an essential tenet of the Jain religion,” in which case, if the answer is in the affirmative, then the practice is “protected by the right to religion under Article 25 of the Constitution of India.” The Court cited *Gian Kaur vs. State of Punjab*, which held that, “The right to life does not include the right to die. The right to human dignity does not include the right to terminate natural life...” Further, whatever American and European conceptual and practical distinctions made between active and passive euthanasia, the Court reminds that the Supreme Court of India has “held that both euthanasia and assisted suicide are not lawful in India,” the latter permissible only through a legislative act that is for the time being wanting. In this sense, then, the analogical reasoning to permit the practice of *santhara* is not equivalent to that which authorizes passive euthanasia. Currently, the law of India does not criminalize refusal of life-saving treatment.

Notably, the Supreme Court of India has acknowledged the legal difficulty of dealing with the question of permission to die when an individual wishes to discontinue life support. A procedure specified by the Supreme Court must be followed. The procedure includes review of the case by a medical committee that includes a psychiatrist, a neurologist, and a physician, with the Court then having authority to issue its decision, “keeping in view the best interest of the patient.” The implication here, then, is that under the law established hereby even a Jainist seeking to

perform *santhara* must petition the Court and accept the judgment rendered as to permissibility of death. That said, the Court concedes that the “antiquity of Jain religion and Santhara is unquestionably proven by its mention in the ancient scriptures.” The Court concedes, furthermore, that Jain religion is “equally modern and rational in its philosophy and approach.” However, at issue in the Court’s judgment is whether the practice of *santhara* is “an essential religious practice”—“without which the following of the Jain religion is not permissible.” The Court concluded that it does not find the requisite evidence to allow this claim; nor have respondents established the matter at issue with the requisite evidence: “It is not an essential part of the philosophy and approach of the Jain religion, nor has been practiced frequently to give up the body for salvation of the soul.” The Court’s judgment is starkly clear: “We are unable to accept the submission that the practice of ‘Santhara’ or ‘Sallekhana’ as a religious practice is an essential part of the Jain religion, to be saved by Article 25 or Article 26 or Article 29 of the Constitution of India.”

The dire consequence of the Court’s judgment is that the petitioner’s writ is accepted, that any form of *santhara* practiced by the Jainist community is punishable under the Indian penal code, that the State authorities are now directed to “stop and abolish the practice of ‘Santhara’ and ‘Sallekhana’ in the Jain religion in any form.”

The Moral Issue

The decision taken by the Indian court does not prejudge the outcomes of debates in India about either euthanasia in general or physician-assisted suicide. These debates remain inconclusive. Accordingly, the Court recognizes the right of the legislature to settle the matter through an appropriate legislative act of that body. However, the decision of the Court, the ongoing lack of consensus among the Indian public, and the lack of legislative initiative do not eliminate the moral and philosophical issues here. Law and morality remain inextricably bound in any democratically constituted government; and so, this is the case with India. At the moment, because the matter under review appealed to a question of constitutional law, the Court could not but settle the issue in the way it did. But, one can consider the moral question at hand differently; because the “rationality” associated with the question at issue can be engaged in way other than that of positive law.

Those who adhere to, or otherwise find good reason to tolerate, religious beliefs such as those held in the Jain religion yet have moral standing to speak to the question at issue in light of prospective legislation. The Court has not settled the normative question, since this involves one or another moral account separate from the legal account. Hence, one may ask here what constitutes a reasonable *moral rationality* to be juxtaposed—and even contraposed—to the legal rationality that grounds the Court’s approach to the practice of *santhara*.

The above point about rationality issues from an engagement of the epistemological problem of divergent rationalities and divergent concepts of justice about which the prominent moral philosopher Alasdair MacIntyre reminds us in any number of his works. In his *The Tasks of Philosophy*, MacIntyre (2006) contributes a chapter entitled, “The ends of life, the ends of philosophical writing.” There, MacIntyre reminds that, “A text or set of texts may on the one hand engage those who read and discuss it, so that they become inhabitants of its conceptual world and formulate their questions only in its terms, so that, as it were, their world becomes text and their inquiries are no longer about the ends of life, even when these are the subject matter of the texts in question, but only about *the-ends-of-life-as-conceived-within-this-particular-textual-universe*.” [p. 127] Thus, this is what has happened with those who are recipients of the Court’s decision. The basic philosophical question concerns what may or may not be done with respect to the ends of life, but this basic question is now marginalized by the dominance of the legal texts, despite a review of religious and scholarly texts that speak to the issue of Jainist metaphysics and religious practices. This is an important consideration, as a matter for philosophical interrogation, because, as MacIntyre clarifies, it is not only the text or texts that are at issue, but the fact that the text is “read through layers of interpretation.”

There is a *hermeneutic obligation* presented here—viz., to avoid becoming “imprisoned within a textual world,” when the life-world with its questions about the ends of life remains central and pressing to the philosophical and moral inquiry. Anyone seriously engaging the Court’s decision must move beyond that text and its rationality to consider what the Jainist practitioner finds paramount about the ends of life, including here the end that presents itself metaphysically and physiologically as death through an act of *santhara*. The point is not to *contest* metaphysical claims from the point of view of some standard of truth (correspondence, coherence, pragmatic, etc.), but to *acknowledge* that the questions at issue have rival answers that are lodged in one or another rational commitment. This includes the moral philosophy or moral theology that is at play in the disputation about meaning, about ends, and about the correct (morally permissible) means to achievement of those ends.

It matters, for example, that in the case in India, the petitioner is a practicing lawyer, in which case his prejudice (taken here positively, not negatively) is one of law, not that of morality *per se*. This petitioner interprets *santhara* as an act of suicide, in which case, he finds this a criminal act, insofar as it is an allowance and transgression of the right to life protected by the Constitution of India. This is, once again, a legal interpretation. There is no philosophical or moral assessment involved, even as the petitioner is not himself a member of the Jain religious community. The Court recognized the rationality of the Jain

metaphysical system, despite the Court's conclusion about *santhara*. Those concerned with "the ends of life" have reasonable epistemological interest in the veracity of Jainist metaphysics and in the moral value of *santhara* within this metaphysics. That said, it must be remembered that the Jainist is concerned with the ends of life and the means to fulfillment of those ends, having some guidance from the Jainist metaphysics, surely. But, s/he is not concerned with this as a matter of law or legal rationality at all. This concern with the ends of life is what is salient and "urgent," not the Court's legal reasoning or decision as such.

We must remember that the Jainist who takes a vow of *santhara* does so—as MacIntyre would say—under the influence of whatever *cultural ethos* s/he inhabits. For him/her, *santhara* as a rite of the Jain religion has its own immediacy of meaning, without the need for sustained philosophical or moral interrogation. Here one can ask what it means for a Jainist to *live* "an exemplary life" that then *ends* with the practice of *santhara*, as a matter of personal conviction and examination with his/her *guru*, which is itself intermediate (according to Jainist metaphysics) to a subsequent rebirth, soul (*jiva*) joined in rebirth to a new body. The legal approach to the practice of *santhara* does not engage *this* question; nor does the Court's legal assessment engage this question even when concerned to evaluate the variety of texts at its disposal to decide whether *santhara* is an essential part of Jain religion. It is in this sense that the *justice* that is to be realized in this matter, for the individual as Jainist *per se*, is more than what is stipulated by the Court in its interpretation of what is and is not constitutionally protected.

For the Jain who undertakes the practice of *santhara*, the underlying question is not "what does it mean to be a law-abiding citizen of India?" (an answer to this question then being an account of what it means to be a "good citizen") but, rather, "what does it mean to take a vow of *santhara*?" (an answer to this question then being an account of what it means to be a "good man"). These two questions are contraposed such as to disclose the contemporary sociopolitical problem of India's movement to democratic modernity, while having a pluralist culture that includes a diverse religious *ethos*, the latter having its antiquity and, thereby, the authority of traditions of belief and practice long established. Jainist metaphysics has its own rationality, and with this rationality there is a concept of justice installed, such that, given the goal of *atma darshan*, the Court's decision amounts to an interdiction that sets aside the propriety of this goal and the Jainist concept of justice. Both as a matter of principle and practice, the Court's decision transgresses this Jainist concept of justice that issues from the goal of *atma darshan* as a guiding principle within the Jainist religion. Hence, one can ask as does MacIntyre in his other prominent work on this philosophical type question: *Whose justice? Which rationality?* (MacIntyre, 1988)

Here we find the hermeneutic dilemma of "rival justices" and "competing rationalities" that MacIntyre

characterized and engaged: the dilemma that issues from "considering the intimidating range of questions about what justice requires and permits, to which alternative and incompatible answers are offered by contending individuals and groups within contemporary societies." (MacIntyre 1988,1) India has its own "scene of radical conflict," its own "quarrel" between antiquity and modernity, to resolve, if it can, without deferring automatically to the authority of its Constitution and to the interpretations of the courts. Citizens of India, no less than others outside of India, are called upon, as MacIntyre puts it, "*to confront the question: How ought we to decide among the claims of rival and incompatible accounts of justice competing for our moral, social, and political allegiance?*" (MacIntyre, 1988, 2) The positions advanced by both petitioner and respondents in the High Court are party to this more fundamental question, although neither has undertaken this question *per se* so as to provide a meaningful answer to guide either public deliberation, public policy, or public law, much less moral resolution among contesting communities.

The fact is that the legal interpretive framework that informs the Court's analysis does not offer a way out of the hermeneutic dilemma so long as it will merely privilege its own legal rationality and its own constitutional concept of justice. Similarly, merely privileging the practical rationality that belongs to the Jain religion likewise does not offer a way out of the hermeneutic dilemma. The petitioner sought legal relief and thus legal resolution. The Jain's practice presupposes a religious resolution. Each has interpretive prejudices installed in the rationality each privileges, and these are unavoidably incompatible, with attempted resolution of problems of justice already incommensurable therefore. MacIntyre observes, as a point of instruction to us: "*And so when disagreements between contending views are sufficiently fundamental, as they are in the case of those disagreements about practical rationality in which the nature of justice is at stake, those disagreements will extend even to the answers to the question of how to proceed in order to resolve those same disagreements.*" (MacIntyre, 1988, 4)

At issue here is an account of rationality and an account of justice, thus justification of beliefs and justification of practices both at issue under conditions of contested rationality, cultural pluralism, and the installation of modernity yet in quarrel with the antiquity of one or another religious *ethos*. This is a scene of radical conflict that is not unique to India. Yet, the government of India and the citizens of India cannot but move forward with the requisite diversity of deliberation and disputation recognized for what it is, so as then to engage the answer to the fundamental question about the ends of life that the Jain practice of *santhara* has brought to the fore as a matter of rationality and justice. While the Court's decision follows from what is and is not justiciable within the purview of the applicable jurisprudence, outside that framework there is ample reason to find the practice of *santhara* as indeed

essential to Jain religion, thereby to find this practice morally permissible when voluntary and according to customary deliberative vow justified by the metaphysical rationality that governs Jainist religious beliefs and practices.

References

- High Court of Judicature for Rajasthan at Jaipur Bench, Jaipur, "Court Order in *Nikhil Soni v. Union of India & ors.*," Ref. D.B. Civil Writ Petition No. 7414/2006, 10 August 2015.
- MacIntyre, Alasdair, 2006. *The Task of Philosophy, Selected Essays, Volume 1*. Cambridge: Cambridge University Press. pp.125-142.
- MacIntyre, Alasdair, 1988. *Whose Justice? Which Rationality?* Notre Dame: University of Notre Dame Press.

The ethical aspects of *halal* certification of medical devices in Malaysia

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Abstract

The medical devices industry is one of the fastest growing sectors of healthcare industry with a large market, a wide variety of products and growing applications. In Malaysia, this industry is a major contributor to the economy and government initiatives support its growth to position Malaysia as a medical device manufacturing hub in the Asia-Pacific region. There are more than 180 manufacturers of medical devices in Malaysia involved in the production of sophisticated devices such as orthopedic products, surgical instruments and dialysis machines. Local companies are moving towards complying with internationally recognized quality standards such as ISO 13485 as an attempt to penetrate the global market. However, there is a religious need to provide medical devices that are certified *halal* in order to cater to the needs of Muslim consumers who make up 64.3% of the Malaysian population. It is an advantage that Malaysia *halal* certification industry is well-developed and recognized as a model all around the world. Malaysia shows a strong industrial manufacturing potential for a wide range of *halal* products. The availability of supporting industries thus provides Malaysia with the ideal conditions to develop into a medical device hub in Asia as well as to establish a global acceptance model for *halal* medical devices.

This paper will discuss the ethical aspects of developing *halal* medical devices for the needs of Muslims in Malaysia and other Islamic nations.

Keywords: *halal*, certification, medical devices, Malaysia, stakeholder

Introduction

Issue on *halal* authenticity is one of the major concerns for Muslims today. In Islam, an important factor for Muslim consumers is whether a product is *halal* (lawful) or *haram* (unlawful) (Ramin Jorfi et al., 2012). Malaysia is heading towards becoming a main player in the world *Halal* market.

Demands for products with *halal* certification are escalating, in line with the growth of population (Ahmad Nizam Abdullah, 2006). Extensive literature often debate on the determination of *halal* authentication of *halal* food product, cosmetics and pharmaceuticals (Mohammad Aizat Jamaludin et al., 2011). However, up to the best knowledge of the authors, there is still no specific study on *halal* medical devices. Hence, there is a religious need to provide medical devices that are certified *halal* in order to cater to the needs of Muslim consumers who make up 64.3% of the Malaysian population.

The total value of Malaysia medical device export was RM 15.35 billion (USD 4.76 billion) in 2013 representing a 7% increase over RM 14.35 billion recorded in 2012 (AMMI, 2014). In the medical device industry, there are a number of stakeholders who need to have their voices heard throughout the process. Each stakeholder has diverse and unique needs relating to the medical device, the needs of one may highly affect the needs of another, and the relationships between stakeholders may be tenuous (de Ana, Umstead, Phillips, & Conner, 2013).

This study however, differs from the other as the aim is to identify two distinct types of stakeholders involve in developing *halal* certification of medical devices in Malaysia; either direct stakeholder or indirect stakeholder. This paper demonstrates how these stakeholder attributes differ for two distinct categories of stakeholders. This study would be useful for all players in this industry as the findings would help to develop strategies to promote *halal* certification of medical devices in Malaysia.

Methodology

The framework proposed in this study is based on two types of data collection; interviews and electronic references. Preliminary interviews were conducted to the local sutures manufacturer. It took about an hour covering semi-structured questions. The manufacturer was asked about the process of catgut production in order to determine the *halal*-built-in through the production chain and also the procedure to comply the international standard as well as the shariah.

Interview was also conducted to the Medical Device Authority (MDA) in order to have the details on acts and standards related to medical devices to follow as a

guideline to start the halal certification for the medical devices in the market.

Discussion

Malaysia is fully committed to strengthening the Halal industry and achieving the vision of making Malaysia a global Halal hub. Halal is part of Shariah principle and is mentioned in The Holy Quran. Shariah is the code of conduct for the Muslims to follow and apply in every activity (Ab Talib & Mohd Johan, 2012). The definition of halal is permitted, permissible and lawful. *Haram* (non-halal) is the opposite of *halal*, which means forbidden and unlawful in the context of Islamic law. In present, *halal* aspect has become a concern in the production and application of various products. For example meat products, cosmetics products, pharmaceuticals products, services such as banking and finance and tourism. Unfortunately, halal certification for medical devices has not being discussed intensely in the literature.

From a strategic perspective, stakeholder management urges corporation to consider the impact of their action and decision making on the various stakeholders. Stakeholder management, with its underlying business ethics component, focuses on the fair treatment, by the "firm", of its various group of stakeholders: especially of suture manufacturers, doctors, and patients. However, beside these primary stakeholders, there are also important indirect stakeholder such as civil society and pressure groups who defend the interest of specific stakeholder groups. There are also regulators such as law, official institutions and control organisations; and finally the press and other media. The stakeholder approach also has to focus on the need for corporations to inform transparently and through dialogue, especially in its approach to pressure groups.

According to Freeman et al., (2004), stakeholder theory has primarily focuses on corporate responsibility towards a firm's stakeholders. The literatures suggest many classification of stakeholders using various criteria (Vasi & King, 2012). Most classical categorisation, based on priority, refer to primary versus secondary stakeholders (Donaldson, et al., 1995) or normative versus derivative stakeholders (Phillips, 2003).

Stakeholders are those groups or individuals with whom the organization interacts or has interdependencies and any individual or group who can affect or is affected by the actions, decisions, policies, practices or goals of the organization. Primary stakeholders are those who have a formal, official, or contractual relationship, and all others are classified as secondary stakeholders (Gibson, 2000). Primary stakeholders enjoy a direct and contractually determined relationship with the organization whereas secondary stakeholders are at the boundaries of the organization who may be affected on by its actions but lack any contractual connection (Fassin, 2012). The secondary stakeholders are capable of influencing whether the operation is effective (Gibson, 2000). The

implication is that a stakeholder is any individual or group with power to be a threat or benefit. Secondary stakeholders include nongovernmental organizations (NGOs), civil society groups, activist groups, outsiders or social movements (G. A. de Bakker & den Hond, 2008).

Normative stakeholders are those stakeholders to whom the organization has a moral obligation (Phillips, 2003). However, derivatives stakeholders are those stakeholders to whom the organization has no direct moral obligation as stakeholders. These groups cover the competitors, activist, terrorist and the media (Phillips, 2003). They can affect the organization even with no legitimate relationship with it.

According to the perspective of promoting halal certification for medical device in Malaysia, this attempt involve ethics responsibility. Ethically, this duty should be a concern to large groups of stakeholders. In order to promote halal medical devices, there is a need to build a platform for a discussion between both direct and indirect stakeholders for halal medical device standardization (Idamazura, 2014).

Primary stakeholders who should directly be involved in the application of halal medical devices are the manufacturers (local or international), doctors, nurses, and patients. Basically, the manufacturers are responsible to ensure that medical devices manufactured meet or exceed the required standards of safety and performance (Norshakira Ramli, 2014).

The major users of medical devices include the doctors and nurses who employ the medical device only for the intended indications. They also ensure the proper use of medical devices by being a competent user (having appropriate qualification, training and experience). Besides that, doctors and nurses are encouraged to share experience gained with medical devices with others (users, distributors and manufacturers) by reporting any incidents to a coordinating centre from which warnings can be issued (Norshakira Ramli, 2014). The users also need to ensure proper maintenance of medical devices during active use and safe disposal of obsolete medical devices (Medical Device Authority (MDA), 2013).

Patients and healthcare providers embody the engagement of religion with modern medicine on a daily basis. Patients' salient health beliefs and health care choices are often informed by religious values and understandings. Religion also influences the practice patterns of healthcare professionals in both visible and unconscious ways (Curlin, 2008).

However, the secondary stakeholders cover the responsibility carried by the policy maker, which is the Medical Device Authority (MDA), Department of Islamic Development Malaysia (JAKIM), consumer association, and researchers. MDA serves to address issues of health and safety of people associated with the medical devices (Jabatan Perdana Menteri, 2012). Generally, MDA is responsible in establishing and implementing policies and regulations to control medical devices to ensure safe and effective medical devices sold or made available in the country (Nor Idamazura, 2014).

JAKIM is the authority responsible for Halal certification in Malaysia. There is a high potential in promoting halal medical devices in Malaysia since Malaysia's Halal certification issued by JAKIM is globally recognised for its stringent criteria and is regarded as having a strong industrial and commercial set up to produce and market Halal products as well as having strong relationships with the major trading nations of the world, and strong government support (Badrudin et al., 2012). The process of awarding Halal certificates involves not only an official site inspection of production plants but also the examination on the Halal status of raw materials (Badrudin et al., 2012). In order for us to promote halal certification of medical devices in Malaysia, this attempt has to take into account the needs of its various stakeholders and balance their divergent interest (Frooman, 1999).

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References

- Ab Talib, M. S., & Mohd Johan, M. R. (2012). Issues in Halal Packaging: A Conceptual Paper. *International Business and Management*, 5, 94–98. doi:10.3968/j.ibm.1923842820120502.1080
- Ahmad Nizam Abdullah. (2006). *Perception and Awareness among Food Manufacturers and Marketers on Halal Food in the Klang Valley*. Universiti Putra Malaysia.
- Badrudin, B., Mohamed, Z., Sharifuddin, J., Rezai, G., Abdullah, A. M., Latif, I. A., & Mohayidin, M. G. (2012). Clients' perception towards JAKIM service quality in Halal certification. *Journal of Islamic Marketing*. doi:10.1108/17590831211206590
- Curlin, F. A. (2008). Commentary: A case for studying the relationship between religion and the practice of medicine. *Academic Medicine: Journal of the Association of American Medical Colleges*, 83, 1118–1120. doi:10.1097/ACM.0b013e31818c638c
- De Ana, F. J., Umstead, K. a, Phillips, G. J., & Conner, C. P. (2013). Value driven innovation in medical device design: a process for balancing stakeholder voices. *Annals of Biomedical Engineering*, 41(9), 1811–21. doi:10.1007/s10439-013-0779-5
- Donaldson, T., Preston, L. E., & Preston, L. E. E. E. (1995). Theory the Stakeholder of the Concepts, Evidence, Corporation: and Implications. *Management*, 20, 65–91. doi:10.5465/amr.1995.9503271992
- Fassin, Y. (2012). Stakeholder Management, Reciprocity and Stakeholder Responsibility. *Journal of Business Ethics*, 109, 83–96. doi:10.1007/s10551-012-1381-8
- Freeman, R. E., Wicks, A. C., & Parmar, B. (2004). Stakeholder Theory and The Corporate Objective Revisited? *Organization Science*. doi:10.1287/orsc.1040.0066
- Frooman, J. (1999). Stakeholder Influence Strategies. *Academy of Management Review*. doi:10.5465/AMR.1999.1893928
- G. A. de Bakker, F., & den Hond, F. (2008). Activists' Influence Tactics and Corporate Policies. *Business Communication Quarterly*. doi:10.1177/1080569907313381

Gibson, K. (2000). The Moral Basis of Stakeholder Theory. *Journal of Business Ethics*, 26, 245–257. doi:10.1023/a:1006110106408

Jabatan Perdana Menteri. (2012). *Program Transformasi Ekonomi: Laporan Tahunan 2012* (p. 272).

Medical Device Authority (MDA). (2013). Medical Devices : Complaint Handling. Retrieved from http://www.mdb.gov.my/mdb/index2.php?option=com_docman&task=doc_view&gid=60&Itemid=59

Mohammad Aizat Jamaludin, Mahmood Zuhdi Hj Ab. Majid, & Mohd Anuar Ramli, Nor Nadiha Mohd Zaki, S. A. R. & D. M. H. (2011). Realisasi Pandangan Fuqaha Tentang Makanan Berasaskan Nilai Saintifik Semasa. In *Seminar Hukum Islam Semasa VII* (pp. 1–15).

Nor Idamazura, on 7th May 2014, at Medical Device Authority (MDA), Putrajaya, at 3 p.m.

Norshakira Ramli, on 15th May 2014, at Worldwide Medivest Sdn. Bhd., Kapar, Klang, at 10 a.m.

Phillips, R. (2003). Stakeholder Legitimacy. *Business Ethics Quarterly*, 13, 25–41.

Ramin Jorfi, Shuhaimi Mustafa, Yaakob B Che Man, Dzulkifly B Mat Hashim, Awis Q Sazili, Abdoreza Soleimani Farjam, L. N. and P. K. (2012). Differentiation of pork from beef, chicken, mutton and chevon according to their primary amino acids content for halal authentication. *African Journal of Biotechnology*, 11(32), 8160–8166. doi:10.5897/AJB11.3777

Vasi, I. B., & King, B. G. (2012). Social Movements, Risk Perceptions, and Economic Outcomes: The Effect of Primary and Secondary Stakeholder Activism on Firms' Perceived Environmental Risk and Financial Performance. *American Sociological Review*. doi:10.1177/0003122412448796

Revisiting Peter Singer's Controversial Argument in *Animal Liberation*

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In this paper, I will question Peter Singer's position on the moral equality of all species. In order to highlight how mistaken he is, I will apply this issue in the use of animals in medical research. Lastly, I will offer a softer position compared to Singer that advances animal well-being without Singer's prejudice against the other members of the human species.

Human Dignity and Moral Equality

According to Peter Singer, the idea that human beings and only human beings possess an inviolable value is unfair. He writes in *Animal Liberation*: "The belief that human life and only human life is sacrosanct is a form of speciesism...The only thing that distinguishes the infant from the animal, in the eyes of those who claim it has a right to life, is that biologically, it is a member of the species *Homo sapiens*."³⁴

³⁴ Peter Singer, "Animal Liberation," in Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002), 86.

Speciesism is a violation of the basic principle of equality. The reason is that it unduly favors human animals in terms of the right to life. Non-human animals, which are unable to defend themselves in a rational way, are thereby put in a familiar disadvantage because they cannot speak for themselves. In this regard, the idea that those non-human animals are less than human puts the former at the lower end of the ladder of evolution. Since non-human animals are not endowed with intrinsic moral worth, it makes using them or manipulating them inside the research lab, morally acceptable.

What is Singer's position regarding the above? Let us revisit Singer's controversial argument in *Animal Liberation*. He says: "*The life of every human being is sacred. Yet people who would say this about the infant do not object to the killing of nonhuman animals. How can they justify their different judgments? Adult chimpanzees, dogs, pigs, and many other species far surpass the brain-damaged infant in their ability to relate to others, act independently, be self-aware, and any other capacity that could reasonably be said to give value to life.*"

There is no mistake in Singer's assertion that we should be sensitive to animal welfare and that they should be accorded at least the equality of treatment. But Singer here compounds the notion of equality in terms of moral status and equality in terms of treatment. What is morally objectionable in his position above is that he gives more moral worth to non-human animals like a chimpanzee than that of a brain-damaged child or infant. Singer (p.81) complains: "*There are many obvious ways in which men and women resemble each other closely, while humans and animals differ greatly. So it might be said, men and women are similar beings and should have similar rights, while humans and nonhuman animals are different and should not have equal rights.*"

The position that animals are of greater value than brain-damaged infants because some non-human animals like chimpanzees have higher thinking skills than these infants is morally problematic because it seems to suggest that moral worth proceeds only from mental functionality. Singer's above argument suffers from two dangerous flaws. First, it identifies the dignity or moral worth of the human person with that of a human person's functional mental capacities. Second, Singer wrongly assumes that the higher "thinking" capacity of nonhuman animals gives them a moral status equivalent to that of a human person.

The dignity or moral worth of any man or woman does not proceed from his or her mental skills or capacities. Our dignity comes from our intrinsic value as persons. Singer opines that the idea of personhood can be misleading.³⁵ This happens, he argues, when it is taken to mean interchangeably as "human being." For him, a person is an agent or one who plays a role in life. As such, he argues that a brain-damaged child fails

such a criterion. But I protest that the functioning of our brain has nothing to do with our moral worth. While a brain-damaged child has less autonomy in terms of making judgments or somehow, none at all, due to a physiological condition, nothing about it diminishes his or her value as a human being.

Singer may argue that brain-damaged children are incapable of reciprocating or of choosing a future for themselves, and so they have less interaction say compared to active dogs, but the fact of the matter however is that such a situation actually motivates family members and others human beings to be more compassionate about their children. The incapacitated infant in this regard is not excluded from that community of beings although he or she cannot physically move. Beyond the notion of utility, our humanity does not come from our usefulness in this world. Of course, objects matter because of their functions. But humans are not objects. We are humans because of the fundamental uniqueness of each and every single human life. This uniqueness does not come from our mental capacity. Rather, it emanates from the unique way as to how each human life is lived and shared with others.

While it is true that the brain-damaged child may not be able to perform the tasks that a "bright" monkey can, but in the same manner, a "bright" monkey also cannot also render the deep joy of parenthood, for instance, in the basic recognition that there is a human life out there that is a value in itself, because, however difficult the condition, your child's life is irreplaceable. While it is not objectionable that we should minimize the pain and suffering of non-human animals, assessing the issue from the point of view of moral equality, to say the least, is morally problematic.

The use of Non-human Animals in Medical research

Now, Singer's position with respect to moral equality becomes all the more a matter of moral concern when it is applied in the case of using non-human animals for medical research. It is a matter of fact that every modern advance in medicine, every new drug, new operation, new therapy of any kind, must sooner or later be tried on a living being for the first time. Prohibiting the use of non-human animals in any experiment for biomedical research, according to Carl Cohen, or sharply restricting it, must result either in the blockage of much valuable research or in the replacement of animal subjects with human subjects. There are very serious consequences, "unacceptable to most reasonable persons," Cohen argues, "of not using animals in research."³⁶

The use of non-human animals in medical research, says Cohen, are justified since animals have no moral or political rights. For Cohen, to have a right means to make a claim. It is a claim that one party may exercise against another. You have the right to demand from

³⁵ Peter Singer, *Practical Ethics*, 3rd edition, (New York: Cambridge University Press, 2011), 74

³⁶ Carl Cohen, "The case for the use of animals in biomedical research," in Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002), 98.

your government, as an example, the just and equitable distribution of welfare benefits. Furthermore, the content of any claim should be fully understood by each party. Non-human animals are incapable of understanding any moral claim.

For Cohen, the lack of rational capacity restricts non-human animals from making any plausible legal claim against another. Whatever rights may be, Cohen (p.94) suggests, they are necessarily human; their possessors are persons, human persons. Human beings have that unique capacity for moral judgment. For Cohen, humans are possessors of reason; non-human animals are not. Humans are autonomous moral subjects; animals are not. For this reason, for Cohen, animals cannot have legal rights. Cohen adds: *"Humans have such moral capacities. They are in this sense self-legislative, are members of communities, governed by moral rules, and do possess rights. Animals do not have such moral capacities."*³⁷

The above means that humans do have moral obligations on others. Since human beings are capable of moral reflection, they can assess or evaluate the consequences of their moral judgments. As such, human beings can distinguish between right and wrong, between good and evil. Non-human animals, however, following Cohen, lack these attributes. For this reason, non-human animals cannot be conferred the same moral status as humans. William Baxter offers a strict anthropocentric position in this case: "The point is this: questions of ought are unique to the human mind and world, they are meaningless as applied to nonhuman animals."³⁸

So if medical research aims at promoting the greater welfare of human beings, and granting that there is no greater value than human life, then the use of non-human animals in medical research is acceptable. If non-human animals are not utilized in biomedical research, then we may not be able to undertake biomedical studies that can potentially save thousands of lives later. While computer simulations may be considered as a matter of replacement or while lines of stem cells offer some significant advance in the field of biomedical research, the argument still stands that from a utilitarian point of view, the utilization of non-human animals in the meantime have actually contributed to the greater good and very survival of the human species.

While we have to be considerate of the fact that non-human animals indeed do suffer in the course of medical experiments, the moral good or value of medical research cannot be substituted for a concern on whether or not a rat, rabbit, or a dog feels pain. Singer's argument on the moral equality of all animals is misplaced because he tries to elevate the status of non-human animals by being prejudiced against members of the human species who are disadvantaged by physical situations that are not of their own

choosing. Singer is simply mistaken in equating the moral worth of non-human animals with that of a human being.

The Principle of Non-harm and the Case for Animal Rights

Tom Regan proposes a softer position with respect to animal rights and well-being. For instance, Regan puts into question the issue in terms of the unacceptability of the system in which we treat animals. Regan notes: *"Factory farming, they say, is wrong. It violates animal rights. But traditional animal agriculture is all right. Toxicity tests of cosmetics on animals violate their rights, but important medical research, cancer research, for example, does not. The clubbing of baby seals is abhorrent, but not the harvesting of adult seals."*³⁹

For Regan, the fundamental wrong is the system that allows us to view animals as our resources, here for us, to be eaten or surgically manipulated, or exploited for sport or money. This strictly "means to an end" argument counters the moral justification that seeks to advance the use of non-human animals for the well-being of the human species.

But it can be argued that our common understanding is that people have no direct duties to animals. We think that we can do animals no wrong. For instance, if someone will kill your goat, someone has done something wrong to you, but not to your goat. Killing your animal henceforth means violating your rights over your goat which you as the owner are entitled to.

Thus, Regan says that it seems that *"as for animals, since they cannot understand contracts, they cannot sign contracts and since they cannot sign, they have no rights"*.⁴⁰ The right to life then implies the direct duty not to harm any human life. In the case of animals, our duty is to the owners; to animals there is only an indirect obligation. While the obligation is indirect, Regan proposes that non-human animals should not be used as mere instruments.

Based on the foregoing, it seems to me that the idea proceeds from the fact that using animals harms them. So the moral argument herein should be the principle of non-harm. Let me explain the principle of non-harm. In both Singer and Regan, while moral capacity is absent on the part of non-human animals, such does not entitle human beings to harm the latter. Singer's problem however is that he is questioning the use of non-human animals by comparing and equating their moral status to that of a brain-damaged child. He even suggests that sacrificing the unique life of that child should not alarm any of our moral or cultural sensibilities. By proposing infanticide, he seems to say that it is acceptable to harm a defenseless infant. Therefore, he is saying that it is sometimes moral to kill a human being if that

³⁷ Ibid. 95

³⁸ William Baxter, "People or penguins," in Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002), 130.

³⁹ Tom Regan, "The case for animal rights," in Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002), 89.

⁴⁰ Ibid. 90

human being does not or cannot reciprocate in the same manner as an active dog. He commits more harm too by saying that it is more immoral to kill a dog.

But can we not promote the idea of advancing and protecting the well-being of non-human animals without making comparisons? Dogs and other household pets have been known to develop bonds of friendship with children, including children with special needs. We can also say that policies may be developed in order to protect non-human animals from abuses. These policies do not in any way prejudice the relationship between humans and non-human animals alike.

In rectifying Singer, what is morally tenable is to maintain that it is unjust and morally wrong to kill any human being because each and every human being is a person. Unarguably, this position does not prevent one from also saying that it is also unjust or morally objectionable to kill non-human animals. The principle of non-harm applies in both instances.

References

- William Baxter. "People or penguins." In Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002).
- Carl Cohen. "The case for the use of animals in biomedical research." In Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002).
- Peter Singer. "*Animal Liberation*." In Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002).
- Peter Singer. *Practical Ethics*. (New York: Cambridge University Press, 2011),
- Tom Regan, "The case for animal rights." In Daniel Bonevac, ed., *Moral Issues Today* (Boston: McGraw-Hill, 2002).

Nurturing medical ethics and professionalism through life experience: 'A day in a doctor's life'

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Abstract

The teaching and learning on medical ethics and professionalism had been discussed as a process beyond the boundaries of lecture halls. It is a component in medical education that should not be focused on theory alone but more on inculcating it as a work culture in future career of a graduates. In Universiti Sains Malaysia (USM), the basic theory and principles had been well scheduled as part of the curriculum activities, but additional non-lecture activities were also arranged to emphasize the application of it. 'A day in a doctor's life' program is a program where a group of year 1 medical students were assigned to a

volunteered medical lecturer. They will follow all the lecturer's clinical duty such as ward round, clinic, operations and patient education session. This paper describes the qualitative findings from the students' reflection diaries. The students wrote about their observation on how the doctors communicate differently in different situation and with different type of patient, how they realize that doctor may not cure always but the doctors' act give the comfort that the patients' need and how they realize that a doctor's job must be carried out with caring, determination and dedication that will overcome all the challenges in medical profession. These observations were more meaningful for them in pursuing their medical profession dream.

Keywords: Professionalism, Ethics, Education

Introduction

Medical ethics teaching had always been emphasized in our Medical Degree curricular. The teaching is spread continually throughout the five year study period. There are always debates on whether professionalism and ethics can be taught, who is the best person to teach, how best to teach and how to assess the learning outcome. We believe that we can nurture the professional behavior by blending the theory with application of it in real life event by making our future professional aware of the ethical culture in this field of medicine. Prober and Heath (2012) proposed way of changes in teaching our future doctors such as simulation and case based exercises. These activities do not replaced lectures but enable teachers to actually teach rather than giving speeches. These multidimensional methods will allow lecturers to perform other role of teachers, i.e. role model and learning facilitators (Harden and Crosby, 2000).

The year one Medical degree program in Universiti Sains Malaysia (USM) begins with bioethics and social health block. Lectures on professionalism, principles of medical ethics, good communication skills are among the lectures scheduled. Apart from these academic activities, The Students Personal and Professional Development Program had arranged a program called Hospital attachment: A day in doctor's life. This program aimed to give the first exposure to the new students on routine work of a doctor, the variability of tasks and the importance of professional behavior in medical practice.

Methodology

This paper described the reflection by the year 1 medical students from three academic sessions from 2011 to 2014 who were involved in the hospital attachment. Students are divided into small groups of ten and assigned to a clinical lecturer who volunteered to participate. The students will follow all activities that the lecturer was involved in from morning to evening and even night calls. Clinical departments involved are internal medicine, pediatric, general surgery, otorhinolaryngology, ophthalmology, orthopedic, neuroscience, plastic and reconstructive surgery, obstetrics and gynecology and emergency medicine.

The students were asked to observe and later report their observations in a group reflective diary. They are asked to describe what they had observed and what they had learned from the observation. Thirty eight reflective diaries were reviewed for the underlying themes by three coordinators.

Findings

Four themes were found from the content analysis. These are professional behavior; empathy, caring and humanity; teamwork and communication skill. The physician professional behavior that had been observed is the adherence to ethical and moral standard, accountability and commitment (Table 1).

Table 1: Physician professional behavior observed

Professional Behavior	Students' reflection [Examples]
Adhering to high ethical & moral standards	Dr R reminded us to treat every patient equally regardless of status, race and religion "everyone has the right to receive a treatment, no one should be discriminated"
Exercising accountability for oneself and for colleagues	Although the staffs were busy, they still put on the sweetest and welcoming smile. Dr I stressed that sometimes we have to work with people from other departments so it is crucial for us to build a good rapport with them I learned a lot – punctuality, dedication, patience and emotionally strong
Demonstrating a continuing commitment to excellence	They portray love and passion in what they do, which is an example of proving that they have a career, not a job Dr N told us -'we can only try our best to save people, but whether the person can survive, it is not in our control'
Exhibiting a commitment to scholarship and advancing the field	It is not as easy as ABC to indicate the real disease. From time to time a doctor had to recall and update their knowledge. For us, it is really cool!
Dealing with high level of complexity and uncertainties	The doctors and the health care team work very hard to approach the problem faced by every patients, with efficient communication, discussion of diagnosis and development of thoroughly thought management plans

Humanistic values are well observed by the students who reflected the observation of honesty, integrity, empathy, and caring (Table 2).

The students also reported observations of teamwork in the daily work of a doctor. They observed how doctors work together between specialists and other health care personnel in making decision for the best care of the patient. They also noted a shared

mental model on teamwork blended with mutual trust (Table 3).

Table 2: Humanistic values observed by students

Humanistic values	Students' reflection [Examples]
Honesty & integrity	Finally we realized the reality of being a doctor – full of tiredness, irregular working hours and continuous learning but when you do your job properly and sincerely you will get all the satisfaction Their concern towards their patients show how strongly sincere and committed they are towards what they do for a living.
Caring & compassion	I was amazed with their (doctors and staffs) knowledge and the way they treat their patients. They show respect, love and commitment at the same time Dr S treats patient friendly. The old medical record was reviewed even though it is thick as the Guyton book Dr R was really patience and nice to her patients and even though I've met unfriendly doctors before this, her attitude completely changed my perspective and I made myself a promise that I would treat my patients just the same way when I become a doctor in future
Altruism & empathy	Dr A showed us to an old man with prostate cancer. It a sad case and at the end we felt empathy towards the old man and his family The patient is a type 2 diabetes patient who had undergone a left leg amputation. She doesn't want to get treatment and gave up her life. Dr A was so understanding and calm. Poor she couldn't even move her legs. We give her motivation to move on. There was a man being catheterized as he had difficulties going to the bathroom. "ouch!" I flinched at the thought of experiencing it myself. Guess that's what they call empathy, no? We noticed the elderly woman in the bed looking rather more ill than the others. A woman in her twenties was at the bedside, tears gleaming in her eyes. Further at the foot of the bed, a young man was having serious discussion with a doctor. Dr Y whispered to us that the old woman had a terminal illness and was in critical stage. But despite all that was going around her, the elderly woman exudes strength and courage that seems to infect us all.

Table 3: Teamwork skill and attitude observed by students

Teamwork skill and attitude	Students' reflection [Examples]
Adaptability	I had the opportunity to observe how the specialists discussed and exchange views in trying to diagnose a patient. It needs not only wide knowledge and experience but also need cooperation and compensatory behavior with respect to each other
Team/collective orientation	"Doctors' don't work alone" – work hand in hand with nurses and other personnel
Shared mental models	We learned that an organized environment and teamwork is strongly required – every team member had to play their role well to ensure task is done well
Mutual trust	In order to solve the patients cases, doctors need to cooperate with each other as a team and discuss among themselves to figure out the best solution and medication for the patients. It showed us the importance of teamwork and cooperation among colleagues

Students also observed the doctors and team members communicate with patients and the care givers. They observed from the process of developing rapport, gathering and sharing information to establish a shared understanding between the physician and the patients on the management (Table 4).

Discussion

Good professionals not only learn during the students years in classroom but continue to learn when they start working through years of experience in managing patients and following examples from the more experience ones. It took years of life experience to mould a physician into a professional; a doctor who does not only have knowledge and skill but who will behave professionally. A physician behavior such as adherence to ethical and moral values, humanistic values, accountability, and commitment defines medical professionalism (Walsh and Abelson, 2008). Humanistic values include honesty and integrity, caring and compassion, altruism and empathy, respect towards others and trustworthiness are values to learn through life experience rather than just theory supplementation.

Health care workers perform interdependence tasks in achieving the common goal for the best care of patients. They have to work together even though they may not undergo the training together (Baker et al,

2005). Students communicate with each other and with their teachers on medical problem, but they have to learn how to communicate the medical knowledge and information to their main client which are the patient and the care givers. These include the essential of communication tasks, i.e. building the doctor-patient relationship, opening discussion, gathering information, understanding patients' perspective, share information, reach agreement on problem and plans and provide closure (Kalamozoo consencus, 2001). Team work and communication skills needs more than just theory. Other mode of teaching such as problem based learning and formal curriculum have the limitation of giving the practical part of this. It was observed in this program that students are able to observe and absorbed the values. Thus, we teachers have to provide the life experience and be the role model to our students. These observations were more meaningful for them in pursuing their medical profession dream.

Table 4: Elements of communication observed by the students

Elements of communication	Students' reflection [Examples]
Developing rapport	Conversation may begins with a simple "how are you?" to make patient feel at ease. It's funny to see the doctor interact with the granny; she really is good at winning his heart so that it is easier to treat him later. I was so excited to see Dr R communication skill to persuade the patient to cooperate for the physical examination
Gather, share information	The patient asks many questions and the doctor answer them all. That's how to get a cooperation from a patient, by responding to them and praise for the good attitude they showed
Establishing shared understanding	We watched how she (the doctor) communicated with the patient and her subordinates and how she handled the patient. It is not easy to communicate with a patient especially if we don't understand what they said as it could lead to misunderstanding. So we learn here that we need to understand and clarify what the patients are saying to avoid misunderstanding
Provide closure	We observed how Dr I communicated, gave conscience information on the medications to his patients. He patiently explained the procedures which started with greetings and self introduction.

References

- Charles G. Prober and Chip Heath. Lecture Halls without Lectures – A Proposal for Medical Education. *N Engl J Med* 366;18; 2012 pp 1657-9
- Harden R M and Crosby J R AMEE Medical Education Guide No 20. The good teacher is more than a lecturer –

The twelve role of a teacher (2000). *Medical Teacher* 22(4): 334-347.

Colin Walsh and Herbert T. Abelson. Medical Professionalism: Crossing a generational divide *Perspectives in Biology and Medicine*, volume 51, number 4 (autumn 2008):554-64

David P. Baker, Eduardo Salas, Heidi King, James Battles and Paul Barach. The Role of Teamwork in the Professional Education of Physicians: Current Status and Assessment and Recommendations. *Joint Commission Journal on Quality and Patient Safety*. April 2005, vol 31 No. 4

Essential Elements of Communication in Medical Encounters: The Kalamazoo Consensus Statement. Participants in the Bayer-Fetzer Conference on Physician-Patient Communication in Medical Education *Acad. Med.* 2001; 76:390-393.

Should an Incapacitated Patient's Refusal of Treatment Be Respected? Discussion of a Hypothetical Case

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Abstract

In the present super-aging society, issues concerning what treatment should be given for incapacitated patients have become more important than ever before. This paper discusses whether or not an incapacitated patient's refusal of treatment should be respected. The authors present a complete hypothetical scenario involving a 75-year-old moderately demented man suffering from malignant lymphoma.

Of primary importance are the respect for patient dignity and the protection of human rights. Acts such as coercion, disregard, restriction, and surveillance can be unethical in many situations. The effectiveness of chemotherapy for malignant lymphoma and its adverse outcomes could offset each other, leaving no net benefits for the patient. The patient is vulnerable and this very vulnerability requires the utmost protection and care. However, protection must be sensitive and comprehensive and the protection of his

life at the expense of many other valuable factors is not justifiable. Coercing unwanted treatment would be intrusion, not protection, because of the physical and psychological suffering. When the refusal is explicit, consistent, and stable enough, it should to be viewed as true and current desire.

Due to moderate dementia, the patient has lost his rational capacity, but his emotional capacity remains. If the remaining portion of his personality is rooted in his feelings, these feelings should be respected as much as possible. Those involved in the care of the patients who refuse treatment should not force them to undergo it simply on the grounds that it may be an established standard in their own country. What must be asked first is whether or not forced treatment would promote the patient's subjective well-being. Additionally, treatment decisions should not be distorted due to the selfishness or discriminatory feelings of those involved in his care.

In situations in which patients lack decision-making capacities, overriding the patients' refusals of treatment should be regarded as an exception, rather than a standard course of action. Even in patients who are incapacitated, treatment refusal could stem from the feelings of the individual. Their subjective well-being would not be improved through close observation, restraint, denial, and coercion, the purpose of which they does not understand.

Keywords: Refusal of treatment; decision-making capacity; incapacitated patient; forced interventions; emotional capacity

1. Introduction

In the present aging society, both the number and percentage of patients who lack decision-making capacity have been increasing. Issues concerning what medical care should be given and how healthcare decisions should be made for such patients have become more apparent than ever before. This paper discusses whether or not an incapacitated patient's refusal of treatment should be respected, i.e., a commonly encountered ethical dilemma surrounding elderly patients with moderate dementia (1). Previous case studies in the field of biomedical ethics involving refusal of care by incapacitated patients and their arguments have focused on various difficult issues, such as the difficulty of assessing patient decision-making capacity, disagreements over the treatment plan by concerned individuals, judgments regarding whether or not physicians should use legally-endorsed or forced interventions, the shortcomings of surrogate decisions, the challenge of managing current preferences expressed by incapacitated patients, and the moral responsibilities imposed on physicians (2, 3). However, to the best of our knowledge, little discussion and arguments have been established on whether or not an incapacitated patient's refusal of treatment should be respected, with the exception of issues pertaining to compulsory treatments for psychiatric patients who are dangerous to themselves and/or others.

In this paper we present a complete hypothetical scenario (Table 1), discuss major factors that may significantly impact the response to an incapacitated patient's refusal of treatment, and present relevant questions by referring to the scenario. The authors then address and answer the aforementioned questions and argue that medical interventions should not be imposed upon the patient in the discussed scenario, and that forced treatments should be regarded as exceptions, rather than a standard course of action. The authors also examine selfishness and discriminatory feelings among those involved in decision-making for incapacitated patients.

Table 1. Hypothetical Scenario for Discussion

Mr. A is a 75-year-old man who had retired from a career with a pharmaceutical company. He had developed hypertension 30 years earlier, undergone a surgical procedure for stomach cancer 20 years earlier, and had an acute myocardial infarction with coronary intensive care 10 years earlier. He was diagnosed with progressive Alzheimer's disease when he was 75 years old. He currently has moderate stage dementia.

Mr. A was brought to the hospital by his family due to his poor physical condition. Medical interview and physical examination findings revealed significant weight loss, systemic lymphadenopathy, and fever. He suffered from dehydration and poor nutritional status. Diagnostic tests confirmed the presence of malignant lymphoma, and Mr. A was immediately admitted to the hospital. On admission, he seemed to recognize that he was in a hospital room, but he did not understand his medical conditions or the reason that he had been admitted. This lack of understanding, secondary to dementia, caused his remarks and behaviors to frequently seem inconsistent and unrealistic.

The attending physician explained treatment options for malignant lymphoma to Mr. A's family, but not to Mr. A himself. The physician informed his family that chemotherapy for Mr. A's condition would likely be effective, and would improve his clinical symptoms and prognosis. Alternatively, however, the chemotherapy could cause him to develop acute heart failure and/or renal failure due to the tumor destruction. After discussing the treatment options with the family members, the physician visited Mr. A's room and said to him, "Let's fix your disease."

Every time the treatment for his condition was discussed, Mr. A consistently and repeatedly told his family and physician, "I want to go home without treatment." However, his family wanted him to undergo chemotherapy because they hoped that Mr. A would survive as long as possible. Mr. A had not written any advance directives concerning medical treatments and his family members were not aware of his previous wishes on this matter.

Table 2: Important Questions Regarding the Case of Mr. A

1. *May restraints and close observation be used to carry out chemotherapy?*
2. *Is it fair for Mr. A if he is treated in the same way as patients whose decision-making capacity can improve or be restored?*
3. *Is it justifiable to change current attitudes toward an incapacitated patient's refusal of treatment based on the presence of advance directives, or knowledge of the patient's previous wishes regarding medical interventions?*
4. *Is it appropriate for a patient's family and physician to choose a course of action on behalf of the patient when medical uncertainty regarding outcomes is significant?*
5. *Do the culture and times in which a patient lives justify different courses of treatment for identical conditions?*
6. *Is a patient obligated to undergo chemotherapy against his own wishes on behalf of the family's interests?*

2. Potential Factors Affecting the Response to an Incapacitated Patient's Refusal of Treatment

Several questions related to factors affecting the response to an incapacitated patient's refusal of treatment are in Table 2. In the following sections, the authors use the scenario of Mr. A to discuss several factors that may impact the way that medical professionals and patient families make decisions for incapacitated patients who refuse treatment.

2-1. Necessity of Restraints and Surveillance (close observation)

Mr. A may pull out his intravenous (IV) line because he does not want to stay in the hospital or receive medical treatment. His 30-year experience, which includes surgery and coronary intensive care, might negatively impact his preference for inpatient care to some degree. He may simply forget that he is receiving IV medications due to his moderate dementia, and may make sudden movements in his hospital bed. It is likely that hand mittens, sensors surrounding his bed, and/or a surveillance camera will be used to prevent Mr. A's IV line from coming out or being withdrawn. Hand mittens are a form of physical restraint, and surveillance cameras and sensors are methods of close observation. Chemical restraints, such as sedation, could be used if he showed extreme resistance to treatment. A whole body physical restraint may even be employed if he attempted to leave the hospital against medical advice. Mr. A may experience serious psychological trauma, as well as deep distrust of and anger against both medical professionals and his family. Patients with dementia, such as Mr. A, cannot understand the reasons why medical professionals detain or restrain them. They could be forced to undergo unwanted medical treatment, which causes discomfort and suffering, and due to the inability to recognize either its purpose or significance, their suffering might be intensified. Given

these serious concerns, is it appropriate to use restraints and close observation to implement treatments for a patient with dementia?

2-2. Possibility of Recovery from an Incapacitated State

Attitudes toward treatment refusal by incapacitated patients are likely to change depending on the possibility of patients recovering their decision-making capacity. Whether a patient's lack of such capacity is permanent or temporary is a crucial factor that affects the decision to override or accept the patient's refusal of treatment. Here, decisional capacity refers to the specific acts of comprehending, evaluating, and choosing among realistic options (4). Appreciating the nature of one's own medical situation and the consequences of giving or refusing consent, rather than merely understanding them, is crucial (5). The authors assume that medical professionals and patient family members are likely to force incapacitated patients to receive recommended interventions despite the patient's refusal if the patient's decision-making capacity is expected to recover. For example, it is likely that a severely depressed patient who attempted suicide and refused a psychiatry consultation would be forced to undergo treatment for depression. Similarly, forced interventions such as IV hydration may be used in a patient with transient intensive care unit (ICU) delirium who refuses treatment and oral fluids. This reflects the current convention of providing treatment to help patients avoid further self-harm, and to recover their decision-making capacity, i.e., autonomy. In such cases, the patient will regain decision-making capacity and, in many cases, this coercion is later perceived as beneficial by the patient. The patient would likely appreciate this forced treatment when cognitive function is restored (6), and may even thank the physician for compulsory treatment later on. This, however, is not Mr. A's scenario.

Mr. A's decision-making capacity will deteriorate progressively and never improve, i.e., he will never be autonomous again. Due to the progressive nature of his moderate stage dementia, he will not understand the meaning of his treatment, including chemotherapy and other necessary measures, and will not appreciate those who forced him to undergo chemotherapy. The authors argue that significant ethical differences exist between patients with curable depression or temporary confusion versus patients with Alzheimer's disease like Mr. A, concerning the achievable goals of compulsive treatment. Therefore, the authors question whether justice can be achieved if Mr. A is treated in the same way as patients whose decision-making capacity is likely to improve or be restored. It is also argued that justice requires equals to be treated equally and unequals to be treated unequally in relation to morally relevant inequalities (7). The possibility of recovery from an incapacitated state is a morally relevant inequality.

2-3. Presence of Advance Directives

For the sake of argument, consider the scenario in which an incapacitated, bedridden patient with a severe cerebral infarction suffers from aspiration pneumonia. The patient adamantly refuses IV antibiotic therapy saying, "No more needles, I have had enough and am fed up with it." Unlike Mr. A, the patient has advance directives, which were prepared in an appropriate manner through advance care planning (8). His directives indicate that he does not want any life-saving interventions (including blood transfusions, antibiotics, hemodialysis, vasopressors, or any other intensive treatments) in the event that he becomes bedridden and loses decision-making capacity, and if there is no chance of improving his underlying disease. In this case, some medical professionals would accept his refusal based on the wishes expressed in valid advance directives, which are regarded as important factors in planning a patient's care (9). Others might disregard both his advance directives and refusal given the high efficacy and low burden of IV antibiotic therapy.

In Mr. A's scenario, however, there are no advance directives and no one knows what his wishes would have been regarding aggressive treatment of hematologic malignancy prior to his loss of decision-making capacity. The authors believe that Mr. A's expressed refusal against chemotherapy would be respected in the same way as that of the above case if his advance directives indicated that he wishes to forego aggressive life-saving or life-prolonging treatments in the event that he loses decisional capacity. However, in Mr. A's case, advance directives, which can justify forgoing or withdrawing life-sustaining treatments for seriously ill patients, are missing.

An incapacitated patient with advance directives expressing treatment refusal, who is currently refusing the same treatment, would be considered to be expressing the fundamental values of his character. However, the refusal of treatment by Mr. A, who has no advance directives, could be considered the result of irrationality, confusion, or disorientation due to moderate dementia, although no reports exist on how treatment refusal by an incapacitated dementia patient has actually been dealt with in clinical settings. Healthcare professionals confronted by such refusal may consider themselves in a deadlock, and the predominant course of action is unclear.

It cannot be denied that Mr. A's negative feelings and dim yet unpleasant memories of past inpatient care have driven him to refuse further treatments. Despite having not prepared written advance directives, he may have decided not to have any aggressive medical interventions in the case of future dementia. No one knows. It would be considered unjustifiable for an incapacitated patient's refusal to be ignored if the patient clearly refused treatments and had advance directives that were consistent with the refusal. On the other hand, is it ethically wrong to regard the current wishes of treatment refusal as

stronger evidence to justify forgoing intervention than advance directives written in the past, even if, like Mr. A, the patient lacks decision-making capacity? The authenticity and implications of a moderately demented patient's refusal should be carefully deliberated because the patient lacks decisional capacity. It is also necessary to contemplate what makes the patient refuse medical care and how strongly the current refusal should be considered in the treatment decision.

2-4. Magnitude of Uncertainty

Medical uncertainty refers to the uncertainty of whether the goals of a medical intervention would be achievable. Reliable data concerning success rates may exist, but statistics cannot foretell what will happen to an individual patient. The magnitude of medical uncertainty varies depending on the clinical situation of the patient. In the current case, chemotherapy may alleviate Mr. A's symptoms and improve his prognosis. Conversely, side effects of chemotherapy including vomiting, infection, and loss of hair, and possible subsequent complications including acute heart failure and/or renal failure due to tumor destruction, could aggravate his condition or potentially even be fatal. In such situations, medical decision-making is a gamble. A capable patient would decide upon a course of treatment by considering all possible risks and benefits, with an understanding that the outcome of any decision is uncertain. However, due to his dementia, Mr. A is neither able to understand the risks and benefits of his treatment options, nor choose which intervention he deems most desirable.

In situations in which a moderately demented patient like Mr. A clearly refuses a course of treatment that involves medical uncertainty and significant consequences, are his healthcare providers and family members justified in making treatment decisions for him, against his wishes? The legitimacy of imposing potentially life-saving chemotherapy with possible lethal complications based on decisions by others must be addressed. It is also necessary to balance beneficence and non-maleficence in the care of a moderately demented patient who still retains the ability to feel (i.e., is sentient) and express his or her wishes.

2-5. Standard Course of Action in the Present Setting

Mr. A has voiced his refusal to undergo chemotherapy, stating "I would like to go home without treatment." However, the standard course of action for elderly patients with malignant lymphoma in the society in which Mr. A lives is to undergo chemotherapy. Hence, it is very unlikely that his refusal would be accepted without resistance from those involved with his care. This is because, within Mr. A's society, most people assume that he would want to undergo chemotherapy for his lymphoma if he were capable of rational decision-making. It is common for families and healthcare professionals to

insist that a patient with lymphoma undergo chemotherapy, regardless of patient refusal in this society. In fact, regardless of society, it would likely be very difficult for those concerned to accept refusal by a patient with or without decisional capacity if a rational patient would agree to undergo the treatment.

In contrast, within societies in which the standard course of action for elderly patients with hematologic malignancies does not include invasive or aggressive treatments, Mr. A's wish "to go home without treatment" would be perceived as natural and reasonable. It is very likely that aggressive treatment, such as chemotherapy, is not recommended, and hence the refusal itself may never occur in the first place. In Mr. A's case, he is likely to be admitted due to his temporary poor condition, but would be discharged once stabilized without further treatment recommendations. Therefore, whether or not the patient's wish to not undergo chemotherapy is regarded as treatment refusal depends on the medical standards in a particular setting. Such standards, which affect patients purely by chance, may determine whether or not patient refusals are accepted.

Even in identical medical situations, social acceptance of patient refusals may differ based on the time and place where a patient happens to live. In a sense, social standards at a particular place and time determine the priority of values, and whether or not a patient's treatment refusal is deemed perverse is purely a matter of chance. The decisive power and intentions of family members also differ depending on the time and place in which they exist. The authors question whether it is ethically justifiable or acceptable for a patient's refusal to be treated differently based merely on the place, time, and culture the patient happens to be born in.

In present day Japan, for example, no legal regulations concerning the termination of medical intervention exist, and healthcare professionals are uncertain about which actions or inactions are forbidden. For example, no legally enforceable advance directives exist. Also, when death is not imminent, the right to refuse life-saving treatment is not usually considered. In such situations, when the family's opinion differs from that of the patient, patient intent may not be given priority. "The Principle of Harmony (*Wa no Seishin*)" overshadows respect for autonomy in most human interactions, including clinical ones. Those who are too physically, mentally, or socially weak to express and maintain their wishes are the most damaged by inappropriate medical intervention imposed on them by others, in particular, one's own family (10, 11).

Medical interventions for incapacitated patients may continue as psychological assistance for families in Japan. Family members may want to avoid feelings of regret such as 'We have left this or that undone' after the patient's death, and this regret tends to steer family members away from less aggressive interventions and a "natural course of dying." (12) In these circumstances, medical intervention presents a

purpose for the family to pursue. When interventions or “doing something” becomes the goal itself, rather than a successful outcome for the patient, extraordinary measures never become useless or futile since the alleviation of regret becomes an unconscious benefit for the family. There appears to be an intervention principle involved where doing something is better than nothing, regardless of consequences. However, doing something harmful or burdensome to a patient to ease familial regret is a serious abuse of medical interventions, regardless of the family’s psychological needs (10).

Culture can be regarded as a set of distinctive spiritual, material, intellectual, and emotional features of society or a social group and it encompasses, in addition to art and literature, lifestyle, ways of living together, value systems, traditions, and beliefs (13). The authors argue that respect for cultural diversity is important in the clinical setting, but the value of cultural diversity should not be accepted without questioning when it potentially conflicts with other values such as dignity, liberty, and subjective well-being. Although the meaning of human dignity is ambiguous and various definitions exist, the authors define human dignity as “humanness,” “being free,” “not feeling miserable or humiliated,” and “living without losing human pride” (14).

2-6. Family Wishes

What values are protected by overriding an incapacitated patient’s treatment refusal? If a pregnant woman refuses to treat a medical condition that is harmful to her fetus, forcing her to undergo treatment would protect the life of the fetus, which is highly desirable. If a patient with a highly infectious, deadly disease refused isolation treatment, compulsory treatment would save the lives of others and protect community members. Compulsory inpatient care for psychiatric patients who are a danger to themselves or others also has apparent benefits. If a patient refuses antibiotic therapy for an easily treatable disease that poses a risk of serious or persistent medical conditions, forced treatment may be used to prevent the resulting burden on the patient’s family and society (3).

It can be argued that forced interventions that override refusal of treatment by incapacitated patients are justifiable when direct or indirect harm may occur to other members of society. In other words, common good and third party benefits are prioritized over individual preferences or benefits. In such cases, the incapacitated patient is considered to have a moral obligation to receive unwanted treatments. However, in the case of Mr. A, is it justifiable to force treatment despite his clear refusal? The treatment may save his life, and thus fulfill his family’s wishes that he survive as long as possible. The authors agree that family satisfaction is important. However, can it be claimed, without reservation, that Mr. A has a moral duty to endure unwanted chemotherapy for the sake of his family? The authors argue that prioritizing an

incapacitated patient’s desire over the wishes of the family is a crucial issue that needs to be addressed in real world clinical settings.

3. Selfishness and Discriminatory Feelings

A number of the factors mentioned in the previous section may impact the decisions and actions of those involved in the care of an incapacitated moderately demented patient, such as Mr. A, who refuses treatment. The course of action and decisions made in such situations may change depending on how the questions presented in the previous section (**Table 2**) are answered. The authors posit that selfishness, self-interest, and discriminatory feelings of those involved in the care of incapacitated patients are likely to negatively influence the decisions made regarding the refusal of treatment by such patients.

It can be argued that decision-making by the patient’s family may not be purely patient-centered. There is always the possibility that family member self-interests may distort perceptions of, and judgments regarding, what is best for the patient. Such interests include Mr. A’s pension benefits, which the family will continue to receive as long as he lives; the financial burden of treating and caring for him; or life insurance policies that he may possess. Family relationships may also affect the attitudes of family members. All these issues could lead to biases among family members, and could sway consideration in their favor, even if it is against the best interest of Mr. A. The judgment of benefit is based on value, and both the understanding and perception of what is valuable are likely to change according to personal experiences or backgrounds. Thus, Mr. A’s values are not necessarily the same as those of his family members.

It is also necessary to pay close attention to the discriminatory feelings that family members or healthcare professionals may have toward incapacitated patients, such as those with dementia. It has been reported that such patients suffer from discrimination in healthcare settings (15-18). The authors ask whether possible discriminatory feelings among those involved in the care of incapacitated patients may result in an underestimation of expressed preferences, suffering, pain, agony, or anger in such patients. The authors also present the concern that the family members and healthcare professionals in charge of Mr. A’s care may immediately deem his treatment refusal as not deserving of serious consideration due to his moderate dementia. There is apprehension among some who consider an incapacitated patient’s afflictions to be milder than those of capable patients, or who believe patients’ emotions to be superficial. The lack of consideration for Mr. A’s treatment refusal by those involved in his care could result in forced interventions.

The reality of this situation is that it is impossible to know the inner experiences of an incapacitated patient. Nevertheless, Mr. A could feel as if he was ignored, treated unfairly, or pushed even if he has moderate dementia. His experience would likely be

even worse if he had to be physically restrained. These experiences and situations would be extremely unpleasant as long as an individual is conscious and sentient, regardless of the level of incapacity or age.

4. Ethically Justifiable Decision-Making for Treatment Refusal by Incapacitated Patients

It goes without saying that judgments regarding Mr. A's chemotherapy or other relevant issues should not be distorted due to the self-interests or discriminatory feelings of those involved in his care. Serious efforts must be made to ensure that conscious self-control is employed to prevent biased judgments. In the following discussion, the authors suggest an ethical course of action for Mr. A's medical treatment by answering the questions presented in Table 2.

Of primary importance are respect for patient dignity (i.e., "humanness," "being free," "not feeling miserable or humiliated," or "living without losing human pride" (14)) and the protection of human rights (e.g., respect for human dignity and privacy, prohibition of degrading treatment, right to liberty, and non-discrimination). Acts such as coercion, disregard, restriction, suppression, surveillance, and deception are in principle unethical and unacceptable. Perceived violations of human rights may occur in everyday life or in a clinical setting. Medical interventions and care that involve such behaviors should be permitted only in exceptional situations in which sufficient reasons to do so exist.

Is Mr. A's situation exceptional enough to justify ignoring his refusal and imposing compulsory interventions? The authors do not believe so. Mr. A does not pose a danger to himself or others. The possibility exists that the effectiveness of chemotherapy and the harm resulting from its side effects or complications would offset each other, leaving no net benefits. Nothing is certain and chemotherapy for Mr. A can be called "bet." He cannot understand that his treatment is a bet or appreciate that he has joined in on the bet. Patients with decisional capacity provide their informed consent with an understanding of the uncertainties of diagnosis and treatment outcomes (19). This, however, is not the case with Mr. A. Is it inappropriate for a patient's family and physician to choose a course of action on behalf of the patient when medical uncertainty regarding outcomes is significant?

Additionally, dementia is a major condition that will continue to worsen even if his malignant lymphoma improves. The authors argue that Mr. A's case does not involve an exceptional situation that would justify forced intervention and disregard of his wishes. Because Mr. A cannot appreciate the benefit of chemotherapy, he would likely regard many of its effects as futile, and aggressive interventions would not be justifiable to him.

It can be argued that coerced treatments such as physical restraints could only be justifiable when it is nonintrusive, safe, non-experimental (3). Physical restraints might be acceptable only if no alternatives

exist, and there is a serious danger to the patient or others and if it were used in the least restrictive manner possible and for short duration (20). On the other hand, Mr. A cannot naturally appreciate the necessity of physical restraints and it would incite fear and anger. Moreover, in Mr. A's case, the restraints would not be for a short duration, and he would likely suffer for a long period. Mr. A is not a threat to others, and outpatient palliative care exists as an alternative. Physical restraints, which undoubtedly deprive an individual of freedom, would disregard his dignity in an extreme manner. Thus, the authors argue that both physical and chemical restraints should not be used on Mr. A.

A claim could be made that Mr. A is vulnerable due to his old age and lack of decision-making capacity, and that this very vulnerability requires the utmost protection and care. The authors would argue, however, that protection must be both sensitive and comprehensive, and that the protection of his life at the expense of many other valuable factors is not justifiable. Forcing Mr. A to undergo unwanted treatment would be intrusion, not protection, because of the physical and psychological suffering it would cause. If Mr. A was temporarily vulnerable due to a passing and curable condition, then forced intervention could ensure the protection of his future autonomy. In such a situation, forced treatment may be justified because he could later appreciate such paternalistic interventions. The reality of this case, however, is that Mr. A is permanently incapacitated and he will never be able to understand the good intentions of other people. The possibility of a patient recovering his or her autonomy is highly relevant for decision-making in situations involving an incapacitated patient who refuses treatment. The authors argue that justice requires Mr. A to be treated differently from a transiently incapacitated individual, i.e., it is unfair for him to be treated in the same manner as patients whose decision-making capacity can improve or be restored.

The fact that Mr. A refuses treatment, as well as his basic aversion toward chemotherapy, should be emphasized the most in this discussion. As described in the current case, Mr. A's refusal is explicit, consistent, and stable enough to be viewed as his true, current desire. Due to his dementia, Mr. A has lost his rational capacity, but his emotional capacity remains. The authors argue that if the remaining portion of his personality is rooted in his feelings, then these feelings should be respected to the extent possible, provided that they are judged to be true and his own. If Mr. A wants to go home and not receive treatment, this desire should be respected. Those in charge of Mr. A's treatment should attempt to empathetically imagine his feelings and, even if he did not write advance directives or previously express his wishes to refuse aggressive treatment, to respect what he currently wants as a matter of principle. The authors argue that, in Mr. A's scenario, regardless of

the availability of advance directives, his feelings and statements against treatment should be respected.

It is important to remember that the aforementioned impure elements may impact judgments made regarding the best interests of the patient. The management of treatment refusal by an incapacitated patient could vary significantly depending on the culture, nation, institution, or time at which it occurs due to diverse value systems (13). Different approaches may be employed in identical medical situations. For instance, in elderly patients with malignant lymphoma, both aggressive treatment with chemotherapy and non-treatment may be indicated for good reasons. It can be argued that those involved in the care of incapacitated patients who refuse treatment should not force them to undergo it simply on the grounds that chemotherapy may be an established standard in their own country. What must be asked first is whether or not forced treatment would benefit the patient's subjective well-being. The determination of an incapacitated patient's best interests where no clues except current refusal exists is difficult. However, it is unlikely that subjective well-being, dignity, and liberty would be protected through the imposition of something unwanted, particularly in patients with longstanding decision-making incapacity. Thus, medical care based on cultural value systems that deprive an individual of dignity, liberty, and privacy should be prohibited. It also goes without saying that the primary target of medical care is the patient, not the patient's family. The family's interest should not be prioritized over that of the patient. Mr. A does not have a moral duty to receive chemotherapy to satisfy the desires of his family, and adequately scheduled palliative care would not cause any harm to his family.

If forced chemotherapy was initiated without Mr. A's consent in a single case, aggressive treatment could become the established course of action, and other interventions aimed at curing the malignant lymphoma may continue to follow. It is very likely that if Mr. A's refusal of treatment and wish to return home is initially ignored, it will continue to be disregarded in every subsequent step. Mr. A would then be in a situation with no option of turning back. The authors argue that Mr. A may never lead a happy life if forced chemotherapy and ongoing medical interventions continued.

Finally, those who overrule an incapacitated patient's refusal of treatment should be responsible for any consequences of the forced interventions. To force unwanted treatment is to take on permanent and serious responsibilities. Mr. A's sense of well-being depends largely on the experience of comfortable emotions. Could those involved in Mr. A's care alleviate his feelings of distrust, unpleasantness, and confusion in any manner except by giving sedatives or waiting for his emotions to dissipate? The authors do not believe so. It is unclear what Mr. A will require in the future to enjoy a high quality of life. However, the authors cannot imagine that his subjective well-being would improve through close observation, restraints,

denial, and coercion, the purposes of which he does not understand. A better option for Mr. A would be in-home palliative care. Inpatient care, in and of itself, can worsen the symptoms of dementia and aging, resulting in confusion and anxiety, leading to further harm.

5. Conclusions

In conclusion, even in situations involving patients who lack decision-making capacities, overriding the patient's refusal of treatment should be regarded as an exception, rather than a standard course of action, especially when the refusal is explicit, consistent, and stable. Even in patients who are irreversibly incapacitated, treatment refusal could stem from the patient's feelings. Due to his dementia, Mr. A has lost his rational capacity, but his emotional capacity remains. The authors argue that clear and persistent refusal should be regarded as an expression of Mr. A's emotional capacity maintained in his current personality and be viewed as his true and current desire. It would be inappropriate for his family and/or physician to choose a course of action on his behalf. His refusal, which is rooted in his feelings, should be respected. Mr. A cannot appreciate the nature and meaning of medical treatments for his malignancy and they would only cause suffering and agony. Patients should be treated with respect and courtesy, and medical procedures should be avoided unless there are good therapeutic reasons to pursue them (21). A reason that one cannot understand or appreciate is never a good one.

References

- 1 Morris JC. The Clinical Dementia Rating (CDR): current version and scoring rules. *Neurology* 1993; 43: 2412-4.
- 2 Freedman B, *The roles and responsibilities of the ethics consultant: A retrospective analysis of cases* (edited by Francoise B), University Publishing Group, 2000, Maryland, p.27-33.
- 3 James M. Gustafson, Francis C. Pizzulli, "Ain't nobody gonna cut on my head!" In Bette-Jane Crigger preparation. *Cases in bioethics 3rd edition*, St. Martin's Press, New York, 1998, p.186-190.
- 4 Albert R. Jonsen, Mark Siegler, William J. Winslade. *Clinical Ethics*, 6th edition, McGraw-Hill, 2006, Chicago, p61
- 5 Sector for Social and Human Sciences, Division of Ethics of Science and Technology. *Bioethics Core Curriculum. Section 1: Syllabus* Ethics Education Programme, UNESCO, 2008, Paris, 33-36
- 6 Atsushi Asai, Hiroko Ishimoto. Should we respect an incompetent patient's refusal of treatment? *Studies of Advanced Ethics* 2014; 8:25-35.
- 7 p143, RG, Justice, in Boyd ,et al edition, *The New Dictionary of Medical Ethics*, BMJ Publishing group, 1997, London
- 8 Lois Snyder, JD, for the American College of Physicians Ethics, Professionalism, and Human Rights Committee. American College of Physicians Ethics Manual Sixth Edition *Ann Intern Med.* 2012;156:73-104.

- 9 Tom L. Beauchamp, James F. Childress. Principles of Biomedical Ethics. 6th edition. Oxford University Press, Oxford, 2009, p186-7.
- 10 Atsushi Asai, Kuniko Aizawa, Yasuhiro Kadooka, Toshinori Tanida. Death with dignity is impossible in contemporary Japan. *Eubios Journal of Asian and International Bioethics* 2012;22:49-53.
- 11 Sakiko Masaki, Hiroko Ishimoto, Atsushi Asai. Contemporary issues concerning informed consent in Japan based on a review of court decisions and characteristics of Japanese culture. *BMC Medical Ethics* 2014, **15**:8
- 12 Kouzo Ishutobi. Heionshi no susume, Kodansha, Tokyo, 2010.
- 13 Sector for Social and Human Sciences, Division of Ethics of Science and Technology. *Bioethics Core Curriculum. Section 1: Syllabus* Ethics Education Programme, UNESCO, 2008, Paris, 50-52
- 14 Takao Itoh. Physical constraint. Toshiko Ibe (edition), Kenji Hattori, Takao Itoh. Iryorinri no ABC. Medical Friend Sha, Tokyo, 2004, p185-190, UNESCO 2008, 19-21
- 15 Keisuke Akamatsu. Sabetsu no minzokugaku. Chikuma-Shob, 2005, Tokyo.
- 16 Shoko Mukai. Kanja Tsuiho, Chikima-Shobo, 2003, Tokyo.
- 17 John Farndon *Do you think you're clever?* 2009, Icon Books, London, 103-7.,
- 18 Harry Lesser Ageism in *Encyclopedia of Applied Ethics* 1998, Vol1, Academic Press. 87-94.
- 19 Legare F, et al. Core competencies for shared decision making training programs: insights from an international, interdisciplinary working group *J Contin Educ Health Prof.* 2013 ; 33(4): 267-273.
- 20 Toshiaki Hirai. Q&A Three-minute point of legal Decision. Nikkei Medical Edition, Nikkei BP Sha, 2010, 270-4.
- 21 British Medical Association Ethics Department *Medical Ethics Today The BMA's handbook of ethics and law* Second Edition, BMJ Books, 2004, London, p.100.

A Qualitative Study of the Attitudes of Three Selected Groups in Malaysia on ethical implications of Pre-implantation Genetic Diagnosis (PGD)

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Abstract

The introduction of PGD in the clinical setting is a double-edged sword. This technology has great potential to prevent illness and diseases in novel ways, but at the same time it brings about clinical, ethical and social dilemmas. The aim of this study was to investigate and explore the attitudes of the participants regarding ethical issues arising from the use of PGD; including questions on the moral status of the embryo, playing God, optimizing quality of life for future children and the freedom of choice. In-depth interviews using an open ended, semi-structured questionnaire were conducted with 21 selected participants. The responses to these questions were then analysed qualitatively using thematic analysis. Participants from within the medical fraternity unanimously used their vast medical knowledge in reproductive medicine to explain their perceptions on PGD. Whereby, for religious scholars, responses on each theme are constantly related to the possible consequences of PGD toward the unborn embryos, resulting in a variety of responses because opinions on the moral status of embryos differ from one religion to another. Finally, a group of potential PGD users clearly displayed their responses on the themes either from the perspective of religious beliefs or past reproductive histories, which explained the diversity of views on the ethical issues discussed. Their perceptions on the themes described their rather unique approach to the issues that are based on several reasons, which emphasize their commitment to their profession, patients, children or future children, and religion.

Keywords: pre-implantation genetic diagnosis, Malaysia, ethical implications, qualitative study, thematic analysis

Introduction

William (2007) describes PGD as a new reproductive technology that provides parents with choices that are unavailable previously. It enables parents to select embryos based on their genetic characteristics before implanting the selected embryos into the mother's womb thus, prevent illnesses and diseases. PGD however, brings about clinical, ethical and social issues. While there is no doubt regarding the clinical usefulness of PGD for inherited disorders, there is still doubtfulness on its reproductive outcome, which becomes one of the major clinical issues regarding PGD (Kuliev, 2008). This may be due to the clinical and technical factors involved in PGD, which potentially may affect the viability of embryos and the selection process of euploid embryos for transfer. Kuliev (2008) added that due to the limitations of FISH (Fluorescence In Situ Hybridization) technique to test for only a part of the genome also raised some clinical issues related to reproductive outcome of PGD.

According to Shenfield et al (2003), the increasing numbers of PGD have led to three overriding concerns about medical inappropriateness, ethical acceptability and, adequacy of regulatory oversight. Medical inappropriateness questions whether medical reasons

alone are enough for individuals to demand for PGD or for physicians to provide PGD. Ethical acceptability looks on how well accepted are the ethical issues that arise from the use of PGD such as moral status of the embryos or issues of discriminations. And lastly, adequacy of regulatory oversight asks whether the government or medical community has done enough monitoring and supervision together with any existing guidelines on the use of PGD. Cumulatively, there are 5187 clinical pregnancies that gave rise to 4140 deliveries and 5135 newborns [singleton; 3182, twin; 921, triple; 37] (Harper et al. 2012).

Despite being a new technology, the first case of PGD in Malaysia was reported in 2004 (Abdul Rahman, Z. 2006). With little coverage regarding the case, it is not known how members of the public react to such medical intervention. Therefore, it is relevant and important to conduct this study in Malaysia in order to find out how participants feel about PGD, and ethical and clinical issues of PGD, and identifying the factors behind their perceptions of PGD.

Materials and Methods

Twenty-one participants were voluntary participants in this study. Eight of participants were medical experts, whose work involves contact with women or couples undergoing or who plan to undergo PGD and fertility treatment. Seven were potential PGD users, where most of them had personal experiences with genetic diseases, which could be a factor influencing their decision-making regarding PGD. The remaining six were representatives from three different religious organizations where, their views and opinions could potentially influence the views of members of their groups of their congregations regarding PGD.

In-depth interview, using semi-structured questionnaires, were adopted for this study. The aim was to encourage participants to articulate their opinions on PGD using their own terms. For this study, three different sets of open-ended, semi-structure questionnaires for three selected groups of participant were designed based on ethical and clinical issues posed by PGD such as limitation of testing technique in PGD, reproductive outcome of using PGD, moral status of embryos, discrimination issues, safety issues and parental reproductive rights. There is a need to have different set of questionnaires for each selected group because some of the question asked would be more toward medical knowledge, which would not be appropriate to be asking to participant that has no medical background. On the other hand, some question that was meant to explore participant personal experience raising and living with genetic disease would not be appropriate for medical personal where researcher focus more on their medical knowledge and experience using PGD. The design of the questionnaires was guided by a previous review of the literature on PGD and they were consecutively pilot tested.

Interviews lasted between 40 and 90 minutes. Interviews were taped-recorded, and handwritten notes

were also taken during, or at the end of, each interview. All of the interviews were transcribed and the data was thematically analyzed to determine common patterns or issues highlighted by the participants. The categories were refined in the course of reading and re-reading and continuously checking the data for counter-examples and alternatives. With each re-reading, new insights occurred and it became possible to make associations and connections between different aspects of the data. Key words and phrases were noted, and as themes emerged and connections were made in a cynical progression, they were re-grouped in a process similar to that utilized by other researchers (Redshaw et al. 2007). No new themes emerged during the final interviews, indicating that data saturation had been achieved. Quotations are used to illustrate the themes generated by the analysis, to support the interpretations made and to demonstrate the metaphors that appear to be operating in this context (Henwood and Pidgeon, 1992). It is important to note that the opinions expressed by the participants involved in this study cannot be generalized to the entire Malaysian population.

Results

Moral status of embryo

Participants' views on moral status of embryo are ambiguous. Embryo's status could be classified as just an accumulation of cells, a living human or non-living human. For one participant: *'It's depends on ones definition of when does life begin. Some people might view that discarding of embryo during PGD as an act of abortion and some might not.'* (P7)

Discussion on the theme among potential PGD users showed a rather interesting finding. They either discussed moral status of embryo based on the practicality of the technology, which view destruction of embryos during PGD is part of the process therefore; do not place embryo status higher: *'Actually the 'issue' regarding embryo's moral status has not crossed my mind. For me, embryo is embryo. I do not think it as anything else. The destruction of embryo happens during the process because it is part of the procedure.'* (P10)

Or based their discussion on religious values, where, the view of religious ruling body on embryo status ranked higher than their own view on embryo moral status. *'I would prefer to know what does the religious ruling body said about moral status of embryo before I actually make any decision regarding embryo's status.'* (P11)

Religious scholars' views differ according to their religious teaching regarding the moral status of embryos: *'The process of conception itself is a process of which already has a moving direction or development towards personhood. Therefore, it should be allowed to grow and develop naturally. It should be allowed to grow to its potential as human regardless of how it will turn out to be. It is not appropriate to destroy the lives of these embryos just because they might be disabled. Who are we destroying what God has created.'* (P16)

Contrary to the above statement, two other religious scholars with different religious backgrounds stated otherwise: *'In Islam, life is considered as sacred and should be respected. However, embryo is considered as living human only after 120 days of conception in which, in this period the spirit is breathed into it. So you can see embryo that is use in PGD is not considered as life yet because it is only a few days old.'*(P20)

'If the decision to use PGD can end up with happiness for both the couple and having a healthy child fulfills their desire, then it is fine. There is no reason to prevent them from using PGD. After all, Buddhism emphasizes on personal happiness and fulfillment, and also the need to relief others from suffering.' (P21)

Taking Over the Work of God

'I do not see it as trying to play God nor do I think that parents who choose to go for PGD are trying to play God. It is an individual choice. In fact for me, that is an act of courage. Parent is willing to go through an expensive, invasive and risky procedure such as PGD, knowing there is still a small chance that it might fail. I mean, what kinds of parent will you be when you know that you are able to do something to save your child and yet you do nothing about it.' (P1)

In this evocative description, it encapsulates how parents are willing to try anything in order to make sure that their children are free from disease, particularly, life-threatening genetic diseases. For some parents, the trajectory they followed was more of an obstacle race in which they were beset by unexpected hurdles and uncertainty of how their children life will be when the diagnosis was positive for genetic disorder. Therefore, PGD seem to offer them the best solution to their medical needs. However, for other participants, dealing with the uncertainty and unexpected hurdles in raising children afflicted with genetic disorder, reflect the strength of motherhood and beauty of life itself. At the same time, these participants mentioned that their strong faith in the Creator, motivates them to persevere and perform the duty in raising their sick children with joy and thanksgiving as they are able to spend time with their children although it might be shortened by the genetic disease. Based on these explanations, they thus, viewed parents who tried to change the natural process of human procreation via medical intervention as trying to take over the work of God: *'Sometimes, although our children are sick, they always manage to give us joy and happiness despite the struggle we have to go through by taking care of them. I am talking based on my own personal experience of raising my son who is also a Thalassaemia patient.'* (P11)

Living with genetic disease could change people's perception on PGD because they tend to understand what others, who are in the same medical situation like them, are going through. They described that having to live with genetic disease your whole life makes you look at certain issues differently as compare to being born and remain healthy your whole life: *'You can view it as trying to meddling with natural procreation process but*

it depends on the individuals as well because they have their own reasons to do so. And due to my own circumstances, I tend to understand why and I do not want to pass judgment on those who use it.' (P13)

The emphasis for most potential PGD users was on the ability to freely choose whether to use PGD or not without being judge as good or bad parents because reason to use the technology are varied based on their medical needs: *'I also do not want to judge parent who use PGD. Personally for me, these couples just want to do the best they can for their child. As for myself, I won't totally reject the idea of using PGD but at the same time, I am not saying that I will use it.'* (P14)

Religious scholars' views on this theme are varied widely due to their different religious practices and beliefs. Trying to change children based on the parent's desire is like rejecting God's gift and plan in our life: *'How can you not say that it is not trying to take over the work of God when clearly for me they have the ability to select and discard embryos? If they are not trying to play God, then no need to indulge in such technology and just accept the child as it comes.'*(P18)

On the contrary, another religious scholar has a different opinion: *'If it is done for social reasons, it is forbidden in Islam because it does not have any necessity. The act of choosing indicates that we are not pleased with what God has given to us. But if it is done to avoid any disease, it is not trying to taking over God's work but rather our efforts to ensure that our generation is fit enough and will not spread any genetic disease.'* (P20)

In many accounts, the impact of religious teaching and beliefs on staunch believers could be very profound, particularly when it comes to interventions that possibly change the course of human procreation: *'I believe that everything happen for a reason. I accept it as God's plan in my life and if that is the case, I trust that he will provide me with the strength to go through it.'*(P12)

In this, they were aware of the expectation and judgments that can be made about their wish not wanting to use PGD although knowing it can help their children lead a healthier life. For them: *'Healthy or not, as a mother, I will love and accept him/her unconditionally.'*(P11 & P12)

Optimizing Quality of Lives

In describing how PGD could change their life, some participants viewed it as a way to optimizing the quality of life for their future children, particularly for parents who already have one or more children afflicted with genetic disorder, and planning to have more children in the future. PGD could avoid the transmission of inheritable genetic disorders to their future children. These participants regarded such desires as a parent's main responsibility in term of making sure that their children are born healthy, thus do not see the decision to use PGD to optimize the lives of their children as a negative desire: *'Some genetic diseases are very rare and treatments are sometimes very expensive or access to medication is very limited. That is why in*

certain situation, PGD might be the best solution for these parents who wish to avoid the said predicaments thus, avoiding the need to deal with the after care and treatment of the child'. (P6)

Some responses to the topic on optimization of quality of life via PGD are negative because the thought that PGD enables parent to pre-select their future child reflected that it might or could lead to genetic enhancement of children for other reason than medical purposes, leading to "the slippery slope" argument. However, for some participants, the negative perception on PGD, particularly, the notion that PGD can be used for genetic enhancement, arises due to the lack of knowledge on PGD:

'PGD can give parents the perfect child, in term of their health but it does have its limitation. Don't misinterpret PGD as having the ability to produce a 'disease free child'. Yes, PGD can eliminate certain types of genetic diseases but parents have to know what kind of disease to be eliminated. PGD can only work for those who know about their genetic combination and history because it is not a genetic screening but genetic diagnoses'.(P2)

For other participants who are not in favor of using PGD to pre-select their future children's genetic makeup, feel that by doing so, they do not accept their children as who they are: *'If I focus on getting the perfect child, how would my son feels about it since he has genetic disability? I might be sending him a message that he is not good enough just because he is sick'. (P11)*

Extremely high costs of using PGD were expressed by these participants who think that PGD can only cater to certain groups of people who can afford to pay for the service. Fortunately for them, the needs of Thalassemia patients are well taken care of nowadays, as compare to the previous year where knowledge about it and resources was very limited: *'Nowadays, you can do blood transfusion in any government hospital and medication are also charged at a very minimal price, even free for those who really can't afford it'.(P11)*. P11 added, *'Well, my Thalassemia child might not be cured and have to live with the condition all his life but at least it is possible for them to live a meaningful life with these help we received' as we can't afford PGD'.*

Inequity in access to PGD and other new reproductive genetic technologies (NRGTs) is a common concern in most countries that provide these facilities due to the high cost involved (Redshaw et al. 2007). On the other hand, when asked about how they feel about using PGD to provide the optimal lifestyle to their future children, some participants described the decision by parent to use PGD is part of their parental responsibility and effort to find cure for their children: *'For me, PGD is a medical tool used to eliminate genetic disease, thus provide parents like me with the perfect child that we long for....we just want to give the best to our child and try to provide optimal lifestyle for them'. (P10)*

The narrative these participants provided showed how some parents are prepared to do almost anything to have a healthy baby. Their commitment and determination in finding medical alternative indicate their different way of showing their love to their child, which is in contrast to some, where accepting their children as who they are seen as their unconditional love toward their child. However, parents' desire to use PGD to conceive the perfect child, received criticisms from Christian scholars in this study. These religious conservatives claimed that parental aspiration for the perfect child, can lead to the new era of eugenic. According to Abraham (2012), religious conservative claimed that parents' desire to have the 'perfect child' is to avoid the task of taking care for children with special needs, which come with possible burdens and troubles. PGD will no longer be a technology to eradicate genetic diseases but instead, becoming a technology to create children whose future depends on their social features and genetic combination, which are purposely design to provide them with that extra edge compare to the rest of the peers: *'There are some people who have genetic disease, which restricted their movement and limiting their daily activities, or people with disability that make them dependent on others but still enjoy their life. In fact, I do not see anything low about their quality of life'. (P18)*

Rights to decide on reproductive choices

The vast majority of participants supported the notion that parents should be given the freedom to make their own decision regarding their own reproductive choices: *'I feel that it is wrong not to suggest or even inform parents regarding PGD when as physician you know that it provide them with the alternative that they desperately need. How they will decide on it is up to them'. (P2)*

Some physicians feel that it is the right of the parent to decide what is best for their child, especially when the child is still or will be under their care. Although there was also an awareness that some parents might request to use PGD for trivial reasons such as for susceptible condition, they still strongly believe that the final decision whether to use PGD or not is solely belong to the parent: *'Even in the case of susceptible conditions or sibling donors, I do think that it is the right of the parents to choose whether to go for PGD. As long as there is no harm inflicted toward the child, then I think it should be good enough to allow them to use PGD'. (P4)*

Having personal experiences living or caring for individuals with genetic disorder, potential PGD users in this study firmly believe that final reproductive decision should be the right of the respective parents. This is because, they understand what these parents are going through and they believe they need some space to think about their decision without getting any pressure from third parties: *'We do not walk in their shoes so we have no idea what they go through every single day. We can have sympathy on them but we're not the one*

who has to carry the burden. So, why not let them be the one who make the call'. (P9)

For these participants, they are applying their own struggle and hardship having to raise children with genetic disabilities or, living with genetic disabilities themselves, to support their argument that parents should make the decision on PGD. However, increasing rights of parents regarding reproductive decision, at the same time, has increased concerns that it might lead to unforeseen consequences. Christian scholars mentioned their concern on the effects of increased reproductive rights of parents might have on the society at large. They fears that the increase of reproductive rights might lead to what they describes as the 'slippery slope' of PGD. For instance, using PGD for non-medical sex selection raises arguments and concerns on issues related to the potential for inherent gender discrimination, inappropriate control over non-essential characteristics of children as well as inappropriate and potentially unfair use of limited medical resources for sex selection rather than for more genuine, and urgent medical needs (Hersberger and Pierce, 2011). But contradictory to this idea, the Islamic scholars involved in this study viewed PGD as a stepping stone in medical field that can help parents who are in great need of it. Although having no qualms allowing Muslim parents to use PGD, they however, do not think that parent has the total rights to decide: *'Before they decide to use PGD, they first need to make sure that their reason to use the technology, comply with the religious ruling on the matter. And it is also restricted to applications within legal marriage frames according to Islam'. (P20)*

Discussion

One of the most frequently discussed or debated ethical issues of PGD are concerning the moral status of embryo (Robertson, 2003). Participants' discussions on the moral status of embryo displayed diversity including that the embryo is not a living human thus, requires limited status quo but nevertheless, still needs to be respected or, the embryo is considered as a living human, and must not be destroyed and/or, embryo is a living human until certain period of time. Scientifically, the definition of moral status of embryo is very straightforward, which defines the embryo as an accumulation of cells that does not carry any moral status, thus it has limited rights compared with normal humans (Ehrich et al., 2008). However, for those who are religiously affiliated, embryos are either defined as having a soul or not, which explained the participants' acceptance or rejection on the use of PGD.

Due to its capability to enable parents to pre-select their children's genetic makeup, parent who decided to use PGD may be accused of trying to play God. Most of the time, this term is used in a negative way whereby trying to 'play God' is associated with humans trying to interfere with the natural process of human procreation (Jones, 2004). It is interesting to discover that both hostility and rationality towards the procedure are both displayed in this study. For those who work in the

medical scene, the acceptance toward PGD is based on medical evidence on the positive effect of PGD on their patients. However, for potential users and religious scholars, they either accept or reject the notion that an attempt to use PGD is an attempt to take over the work of God or trying to play God.

Participants who reject this notion are normally those who themselves live with genetic disease or are raising children with a genetic disease. Parents or individuals who are in the same situation generally show more empathy and compassion toward others who are in the same situation (Doolin & Motion, 2010). These parents have no control over the underlying genes of their condition and it is not their choice to deal with such tragic disease (Jones, 2004). One of the underlying factors that influenced and motivates their need to search for medical alternatives such as PGD, is the notion of human suffering. This is consistent with a previous study done among women who had, have or are susceptible to breast cancer; those who favour the use of PGD associated the notion of avoiding suffering in their child as one of the reason for their choice (Quinn et al. 2009). For participants that view PGD as humans trying to play God, the influence of religion is stated as one of the reason for their perception. This finding and decision is not something new because according to Watt (2004), some parents are willing to let nature take its course and leave the health of their future offspring to chance rather than making the choice to use PGD.

One of the disadvantages of PGD is the high costs involved in using it and this could probably be one of the main hindrances for anyone who wants to use PGD. However, high cost of the aftercare of children born with genetic disabilities particularly, genetic disease that are very rare and treatment is scarce, can also motivate parents to use PGD. This in fact, a significant finding in this study because high costs involved in the after care of disabled children has not been associated with parent's motivation to request for PGD. The cost of taking care of a child with genetic disabilities might in the long run exceed the price of going through PGD, thus some parents might feel that it is a small price to pay in order to have a healthy child.

Recognising parent's rights to make final decision regarding their reproductive choices, almost all participants in this study, are strong advocates of parent's reproductive decisions. All medical professionals generally identify reproductive rights as a core value during counselling with their prospective patients before using the treatment (Bisecker, 2010). These views are shared by all potential PGD users in this study, despite their difference views on other issues related to the use of PGD. For potential PGD users, their support for parent's reproductive rights is normally associated with their own personal experiences with genetic disorder. When individuals use their own experiences to justify their perception of PGD, it changes the way they look at the technology. Previous study showed that personal experiences and reproductive history are more important determinants of

eventual PGD use than the mode of inheritance or the expected clinical impact of the disorder (Van Rij et al. 2011). Personal experiences and reproductive history are also found to be a reason why some parents believe that they know what is best for themselves and their future children, thus influencing their own reproductive decisions (Hershberger and Pierce, 2010).

Another significant finding in this study is the link between participant's personal experience with genetic disorders and their belief about the appropriateness of individual decision-making on PGD. This is notably an important finding because frequently presentations on personal experience with genetic disorder are generally associated with their own decision-making or motive to use PGD but not as a contributing factors to support the appropriateness of individual decision-making on PGD for others. However, it is worth to acknowledge that despite participants support for individual decision-making, there are few participants who believe that the final reproductive decision should not be the sole right of the prospective parents. These views are based on participants' religious perspective where absolute freedom is non-existent in their religious teaching. Humans do not have the right to determine when a child will be born, who the parents will be, which gender the child will be or when a child will dies as these are all God's prerogatives (Tang, 2008).

Conclusion

Based on the findings, this study showed that there are three factors that dominate and influence the perception of participants during the discussion; medical and clinical knowledge, religious beliefs and personal experiences with genetic disorders. These factors shaped their perceptions on PGD, thus influence their decision on using PGD. The maintenance of religious beliefs and a strong sense of respect to rich Asian cultures is a strong influence to reproductive choices in Malaysia. However, in contrast to this statement, this study showed that some potential PGD users not only place religious beliefs as part of the factor that influence their decision making on reproductive choices but also the practicality of the technology as well as their previous personal experiences with genetic disorder.

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Conflict of Interest

The authors have no conflict of interest

References

1. Abdul Rahman, Z. (27/6/2006). The Star Online (<http://thestar.com.my/news/story.asp?file=/2006/6/27/nation/14658990&sec=nation>)
2. Abraham, C (2012) Unnatural Selection: Is evolving reproductive technology ushering in a new age eugenics? From Saturday's Globe Mill, 17th January 2012. Retrieved from www.theglobeandmail.com/life/parenting/unnatural-selection-is-evolving-reproductive-technology-ushering-in-a-new-age-of-eugenics/articles1357885/?age=all
3. Bisecker, BB. (2010). Reproductive decision-making in the context of mitochondrial DNA disorders: views and experiences of professionals. *An International Journal of Genetics and Molecular Medicine*, 77: pp10-17
4. Doolin, B and Motion, J. (2010) Christian lay understanding of pre-implantation genetic diagnosis. *Public Understanding of Science Journal*, 19(6):pp 669-685
5. Ehrich, K, Farsides, B, Williams, C & Scott, R. (2008) Testing the embryo, testing the fetus. *Clinical Ethics*, 2(4): pp181-186
6. Harper, JC, Wilton, L, Traeger-Synodinos, J, Goossens, V, Moutou, C, SenGupta, SE, Pehlivan Budak, T, Renwick, P, De Rycke, M, Geraedts, JPM and Harton, G. The ESHRE PGD Consortium: 10 years of data collection. *Human Reproduction Update* 2012; 0(0): 1-14
7. Henwood, KL and Pidgeon, NF. (1992) Qualitative research and psychological theorizing. *British Journal of Psychology*, 83: pp 97-111
8. Hershberger, PE and Pierce, PF. (2010) Conceptualizing couples' decision-making in PGD: Emerging cognitive, emotional and moral dimension. *Patient Education and Counselling*, 81: pp53-62
9. Jones, G (2004), Playing God. Scientific, ethical and technological challenges. Retrieved from www.st-edmunds.cam.ac.uk/cis/st-edmunds/jones/pdf/jones-lecture.pdf
10. Kuliev, A. (2008) Clinical and Technical aspect of Pre-implantation Genetic Diagnosis. *Expert Review Obstetrician Gynaecology*, 3(5): pp 591-593
11. Quinn, G, Vadaparampil, S, King, L, Miree, C and Friedman, S. (2009) Attitudes of high-risk women toward pre-implantation genetic diagnosis. *Fertility & Sterility*, 91(6): pp 2361-2368
12. Redshar, M, Hockley, C and Davidson, LL. (2007) A qualitative study of the experience of treatment for infertility among women who successfully became pregnant. *Human Reproduction*, 22(1): pp 295-304
13. Robertson, JA. (2003) Extending pre-implantation genetic diagnosis: the ethical debate. Ethical issues in new uses of pre-implantation genetic diagnosis. *Human Reproduction*, 18: pp 465-471
14. Shenfield, F, Pennings, G, Devroey, P, Sureau, C, Tarlatzis, B, Cohen, J and ESHRE Task Force. Taskforce 5: pre-implantation genetic diagnosis. *Human Reproduction* 2003; 18: 649-651
15. Tang, A (2008), Biomedical ethical decision-making. Retrieved from www.kairos2.com/publication.html
16. Van Rij, MC., Gielen, M., Lulofs, R., Evers, JL, Van Osch, L, Muntjewerff, N, Geraedts, JPM and de Die-Smulders, CEM. (2011) Profiles and motives for PGD: A perspective cohort study of couples referred for PGD in the Netherland. *Human Reproduction*, 26(7): pp 1826-1835
17. Watt, H. (2004) Pre-implantation genetic diagnosis: Choosing the 'Good enough' child. *Health Care Analysis*, 12: pp 51-60
18. William, C., Ehrich, K., Farsides, B. and Scott, R. (2007) Facilitating choice, framing choice: Staff views on widening the scope of pre-implantation genetic diagnosis in the UK. *Social Science & Medicine*, 65: pp 1094-1105

Ethics status of clinical research and trials in developing countries

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Abstract

With the development of economic globalization, more and more clinical research and trials shift from developed countries to developing countries. The globalization of clinical trials also brings some ethical and scientific concerns. This paper discussed some ethical problems of clinical trials in the developing countries including 1) "golden rice" event in China; 2) Informed consent in clinical trials in developing countries; 3) Ethical consciousness in clinical research and trials in developing countries. The essay suggests that the level of medical ethics in developing countries is lower than that in developed countries. How can we improve the ethical consciousness of clinical researchers and subjects and how can we protect patient rights are important problems faced by developing countries.

Key words: Clinical trial; informed consent; Ethical consciousness; developing countries

In the past clinical research and trials were traditionally conducted in developed countries such as U.S and Western Europe. In recent years there is a tendency to transfer these to developing countries. With the development of economic globalization, there is a close link between developed and developing countries in aspects of economy, trade, science and so on. Therefore, clinical research and trial also have a shift from developed countries to developing countries.

Glickman et al (2009) published an essay entitled "Ethical and Scientific Implications of the Globalization of Clinical Research" which discussed "*recent trends in and underlying reasons for the globalization of clinical research, highlight important scientific and ethical concerns, and propose steps for the harmonization of international clinical research*". [1] The authors indicated that the number of countries serving as trial sites outside the United States doubled in 10 years, whereas the proportion of trials conducted in the United States and Western Europe decreased. For example, from 1995 to 2005, trials conducted in Africa were increased from 5.0% to 8.7%; trials conducted in Eastern Europe and Russia were increased from 2.5% to 5.2%. In contract, trials conducted in United States were decreased from 53.8% to 42.6%; trials conducted in Western Europe were decreased from 40% to 36.5% [1].

What causes this dramatic shift? The main reason that clinical trials transfer to developing countries is that the cost is cheap in developing countries. For example, "a first-rate academic medical center in India charges

approximately USD1,500 to 2,000 per case report, less than one tenth the cost at a second-tier center in the United States"[1]. In addition, the low wages of doctors and nurses in developing country also make the human cost reduced. The great number of potential research participants in developing countries also is a great attraction to drug companies.

The globalization of clinical trials also brings some ethical and scientific concerns, for example, the choice of the participants, the transparency of clinical trial results in developing countries, the regulatory oversight of clinical trials, training and experience of clinical investigators, institutional review board quality and efficiency and so on. This paper will discuss some ethical problems of clinical trials in the developing countries including 1) "golden rice" event in China; 2) Informed consent of clinical trial in developing countries; 3) Ethical consciousness in clinical research and trial in developing countries.

"Golden rice" event in China

In 2012, a research paper published in the *American Journal of Clinical Nutrition* caused a great disturbance in Chinese society and aroused widespread concerns.

The title of this thesis is "β-Carotene in Golden Rice is as good as β-carotene in oil at providing vitamin A to children". In this paper, author said they conducted a trial of transgenic food "golden rice" (GR) in Hunan province of China. [2] The subjects were 72 healthy children, divided into three groups. Among them, 24 children were fed with genetically modified food "golden rice". The researchers examined the content of vitamin A in the serum of children. The results show that "The β-carotene in GR is as effective as pure β-carotene in oil and better than that in spinach at providing vitamin A to children." [2] Therefore, "GR may be as useful as a source of preformed vitamin A from vitamin A capsules, eggs, or milk to overcome VAD in rice-consuming populations." [2].

This paper has aroused strong repercussions in China. Many people believe that it is irresponsible behavior to use Chinese children as subjects of transgenic rice. The public appealed to the government to examine the legitimacy of this research. China Center for Disease Control and Prevention (CDC) and other agencies soon released an investigation report. The report says that this transgenic trial is in violation of relevant regulations, research ethics and scientific integrity. The related responsible persons in China were dismissed from their posts.

The main researchers are staff from Tufts University in United States. The investigation of Tufts University showed that although the "golden rice" research data are correct and they also do not find the health and safety risks, but the study itself does not completely follow the rules of the university ethics review committee and the United States Federal regulations [3]. The survey finds that there is not enough evidence to prove that the project was evaluated and approved by the relevant departments of China. Therefore, there are flaws in the process of obtaining informed consent,

including the lack of a clear explanation to transgenic attributes of "golden rice". The researchers made some changes to the research process and the changes did not obtain the approval of the ethics review committee. According to the results of investigation, Tufts University took corrective measures. The person in charge of the project shall not engage in human studies within two years. He needs once again to accept training on human research related rules and regulations. In addition, the university ethics review committee also revised the rules and procedures. Ethics review committee will carry out more detailed audits of future research outside the United States [3].

Actually, golden rice is a good product. There is no problem in this clinical research if viewed only from the scientific point of view, but, there was a deficiency of ethics in this incident. First of all, the effectiveness of informed consent: Informed consent is an important guarantee to protect subjects in human trials. According to guidelines specifically designed to protect children as research subjects, "for children to become participants, permission must be obtained from parents or guardians, and children must give their 'assent'". [4] The content of the informed consent should be in full compliance with ethical standards and should enable the subjects family fully understand the risks and benefits. The ethics committee should examine the content of informed consent, and supervise the process of informed consent. However, the survey results showed that the signed informed consent was just a very simple notice. There is no introduction about real test information, just saying that it is nutritious meals. There was not any information about transgenic rice in the informed consent [5]. The test site is in the mountains of Hunan province. The local residents' educational level is not high. It is difficult for them to understand the information provided by researchers. Thus it is also difficult for them in the balance of risks and benefits. In this case, an effective informed consent is especially important.

Secondly, timeliness of ethical review: The ethical review should have the effectiveness. If the research project exceeds formulary review period, it should re-submitted the ethical review application. Upon giving approval, the project can continue. In this case, the project went through the ethical review in Zhejiang Province in 2003. When the test was carried out, it was beyond the valid period. The project should be reviewed again, but the researchers did not submit the application for review again. In this process, the supervision function of the ethics committee has also become a mere formality [6].

The "Golden Rice" incident exposed problems in the design of relevant laws and regulations. Therefore, the transparency of ethical review should be increased including the whole process of supervision on informed consent. "Golden rice" event is not a simple technical problem, but the contradictions caused by lack of ethics. We should examine and resolve these issues of ethics to guarantee the healthy orderly development of transgenic technology. It is also necessary to introduce

the accountability mechanism into the ethical and publish the whole supervision process.

Informed consent of clinical trials in developing countries

Informed consent is essential in clinical research and trials. Informed consent means that research subjects must make a voluntary choice about participation, based on sufficient knowledge and comprehension about the research design, the risks and benefits, and their rights as participants. Informed means to let subjects understand relevant information, including information disclosure and information understanding. Consent of the subjects should be voluntary, including capacity to consent and free consent. But the quality of informed consent of clinical research participants is different between developing countries and developed countries. Mandave et al (2012) reviewed and compared available data on the quality of informed consent from research in both developing and developed countries. Their review shows that the quality of informed consent depends on the type and amount of information disclosed, adequate comprehension of trial information, and a voluntary decision to enroll [7]. Their data suggest that "(1) *comprehension of study information varies among trial participants in both developed and developing countries, and comprehension of randomization and placebo controlled designs is generally lower than comprehension of other aspects of a trial; (2) research participants report different sources of pressure to enroll, and those in developing countries are less likely than those in developed countries to say they can refuse or withdraw from participation, and more likely to worry about the consequences of refusal or withdrawal.*"[7]

Generally speaking, the quality of informed consent of clinical research participants in developing countries is worse than that in developed countries. The participants in developing countries have more difficulty to understand information about trial design, randomization and placebo controls because these concepts are unfamiliar to them. Participants in developing countries felt they could not refuse or withdraw from the trial. Possible explanations may be deference to authority, cultural norms, or a fear of not being able to access needed care.

Hill et al investigated informed consent in Ghana. In a placebo controlled vitamin A supplementation trial, they explored whether subjects understand the trial and whether they know that not all the capsules provided in the trial are the same. The data suggest that most women in the trial knew that they were taking part in research but that their interpretations of the trial varied. Many women believed they were receiving an active and beneficial medication. Only 13% knew that not all the trial capsules were the same. [8] The complex language and lengthy consent forms may be the reason for this result, especially in populations with poor education. For example, despite extensive training and provision of fieldwork manuals, 17% of the fieldworkers

did not understand the concept of placebo and thought that all the trial capsules were the same [8].

Similarly, other developing countries also have a similar situation. For example, in Gambia only 10% of participants understood the placebo-controlled design in a vaccine trial; in Uganda only 19% of mothers knew that not all of the treatments in a malaria trial were the same; In Haiti only 20% of participants passed an assessment of their trial knowledge, which included whether they knew the purpose of the study, the risks and benefits of participation and that participation was voluntary; In Bangladesh only 48% of respondents knew they were free to withdraw after giving consent. In South Africa only 28% of participants knew the study's aim, 21% of participants understood randomization and 19% understood placebo [8].

Generally speaking, subjects in developing countries have low trial knowledge. The main reason is the lack of education. So informed consent should be simple and easy to understand in these countries. When the participants cannot understand the informed consent, an accurate and unbiased translation should be provided. When trial participants are from rural or social vulnerable groups, informed consent in the design process should seek help from the local community or non-government departments. For example, in the case of Ghana discussed above, "the consent procedure consisted of gaining community consent from traditional leaders at the district and village level, followed by village level community meetings, where senior project staff introduced the aims and methods of the trial and answered questions. In urban areas, community meetings were replaced by radio broadcasts, as meetings often have low attendance in such settings." [8] Therefore, in informed consent process, we should consider the background of potential subjects, the local resources and cultural and educational level of subjects. In order to protect trial participants' right of informed consent, they have a right to be told what they are getting into so that they can decide whether they want to go through with it or not.

China is also a developing country. It is also one of the world's fastest growing countries. All medical rules and regulations in China are in continuous improvement. Ma et al investigated the current informed consent in clinical research in China. The investigation objects are from Beijing Jishuitan Hospital, one of the largest hospital in Beijing, China. They carried out a questionnaire survey in 1691 patients, and analyzed the data according to sex, age and educational level. The results showed that 85% of the patients agreed to provide blood samples and operation specimens for medical research and signed the informed consent; 15% of the patients did not agree to provide blood samples and operation specimens for medical research and did not sign the informed consent. [8]

The author analyzed the reason of informed consent or not consent. Among 1619 voluntarily signed the informed consent, 78% of the people think that the patient should respect the opinion of the doctor, 13% of the people think that donated samples were no harm to

the body, 8.5% of the people think that they should support the medical scientific research work. [9] These data suggest that the doctor's authoritative is recognized by the vast majority of the patients but relative lack of medical scientific research cognition. Among 281 who did not sign the informed consent, the main reasons are that the patients mistrusted doctors' decisions or they could not understand the content of informed consent.

The results indicated that doctors play a leading role in process of informed consent. Thus, the doctor's good moral consciousness and the moral behavior are an important prerequisite and condition of scientific research activities carried out smoothly.

In addition, there are individual differences among patients in cultural, knowledge and professional backgrounds. Even if the doctors try to explain scientific concepts, informed consent is also very difficult to let the patient fully understand. Among 1619 patients who signed the informed consent, those who fully understand the content of informed consent only accounted for 23% [9]. This result may be related to the three reasons. Firstly, most patients are no medical background knowledge. They do not understand the relationship between the biological information resources and development of medicine. The lack of medical knowledge is difficult to make up for in a relatively short time. Secondly, most of the patients can not accurately understand and accept the information because of their lower educational levels. Thirdly, in the process of signing the informed consent, some doctors' language is simple and blunt, the lack of humane care, lack of communication skills, so that make patients with excessive tension and anxiety, are more prone to misunderstanding. To sum up, in clinical research and experiments, informed consent is an important part. The doctor in the informed consent process plays a leading role. So, the doctor should popularize medical knowledge to patients in the daily work. The doctor should be fully informed patients with patiently explanation and good communication. Thus the patient can correctly exercise the right of informed consent, reduce misunderstanding and actively participate in medical research.

Ethical consciousness in clinical research and trial in developing countries

The clinical research thesis is one of the main forms of clinical research results. There are more ethical problems existing in developing countries than those in developed countries. Meng et al. investigated the status of current ethics development in scientific literatures published in the *Chinese Journal of Epidemiology* [10]. They reviewed published papers from 2006 to 2010 to assess the medical ethical issues among the original papers focusing on human trials. The results showed that 29% of papers announced of "informed consent by the subjects", and the proportion with "having had approvals from the ethic committee" announced is only 7% [10]. The papers that said that they "had approvals from the ethic committee" are far less than the papers that reported they had "informed consent by the

subjects". This phenomenon indicates that although the authors have certain medical ethics consciousness, they still need to improve and standardize the ethical behavior in the process of biomedical research.

The authors also compared the changes in informed consent and ethical review in five years. The proportion of the papers announced of "informed consent by the subjects" is increased from 21.3% in 2006 to 40.6% in 2010. The proportion of the papers announcing that they "had approvals from the ethic committee" is increased from 3.2% in 2006 to 10.3% in 2010. [10] In general, there is an upward trend year by year. This change shows that the ethical consciousness of scientific research personnel is gradually formed.

In order to understand the problems in ethics in China, Meng et al also compared the differences between China and America in the areas of epidemiological areas [11]. They reviewed papers published in the *Chinese Journal of Epidemiology* and in the *American Journal of Epidemiology* from January 2006 to December 2010 and compared the ethical issues involved in the papers that focusing on human trials. The results indicated that the papers marked "informed consent by the subjects" were 29% and 38% respectively in China and United States. The papers marked "having had approvals from the ethic committees" were 7% and 63% respectively in China and United States. Among the studies in the *Chinese Journal of Epidemiology*, the proportion of 'informed consent' and ethical review was lower than the proportion in the *American Journal of Epidemiology*. Especially, there is larger difference in the ethical review [11]. These results indicate that there is a big gap between China and United States on the consciousness of informed consent and ethical review.

The authors also compared the changes of informed consent and ethical review in five years between China and United States. The proportion of the papers announcing "informed consent by the subjects" increased from 21% in 2006 to 41% in 2010 and from 38% in 2006 to 41% in 2010 respectively in the Journal of China and United States [11]. These changes indicate that there is an increasing ethics consciousness through five years both in China and America. China's increase is more obvious.

The above comparison shows that in China, ethical consciousness in clinical research and trial is weak. In the clinical research papers, the ratio of mentioning informed consent and ethical review is not high. So I think that we should strengthen the publicity of medical ethics, and show the function of ethics review committees and normative ethics programs. Firstly, we should standardize the procedures of informed consent. Prior to applying for ethics review, clinical investigators must receive voluntary written informed consent. If a researcher is unable to obtain written informed consent, they should obtain verbal informed consent, and submit the certification materials. For subjects without ability, unable to make their own decisions, written informed consent from the guardian or agent must be obtained. Secondly, the ethics committee review function should

be strengthened. The ethics committee of scientific research institutions should strengthen the supervision and management functions. The ethical review should be carried out during the whole process of clinical research project to ensure that the project complies with ethical principles. Thirdly, when clinical research papers publish in academic journals, the status of informed consent and ethical review should be declared in the paper.

Conclusions

With the development of economic globalization, more and more clinical research and trials shift from developed countries to developing countries. For these clinical research and trials, the large population size of developing countries means that substantial numbers of individuals affected by rare diseases may be found, therefore, it is easy to find all kinds of disease subjects. In addition, the low cost in developing countries also is one of the reasons attracting clinical researchers from developed countries. But the globalization of clinical trials also brings some ethical and scientific concerns. This paper at first described an ethical violation event in China - "golden rice" event. Then the status of informed consent of clinical trial in developing countries was introduced. At last, the ethical consciousness in clinical research and trial in developing countries was discussed.

In a word, the level of medical ethics in developing countries is lower than that in developed countries. We should improve the ethical consciousness of clinical researchers and subjects and how we protect patient rights.

References

- Glickman SW, McHutchison JG, Peterson ED, et al. Ethical and scientific implications of the globalization of clinical research. *N Engl J Med*. 2009, 360: 816-23.
- Tang G, Hu Y, Yin SA, et al. β -Carotene in Golden Rice is as good as β -carotene in oil at providing vitamin A to children. *Am J Clin Nutr*. 2012, 96: 658-664
- http://news.xinhuanet.com/2013-09/18/c_117425514.htm (accessed March 17, 2015)
- Munson R. Marist College Edition (9th Edition). *Intervention and Reflection: Basic Issues in Bioethics*. Cengage Learning, OH. Page 17
- Tian X, Yuan H, Ouyang D. Introspection of "Golden Rice" incident. *Chinese Medical Ethics*. 2013, 26: 17-20
- Tian H, Zhai XM. How to treat genetically modified crops correctly - reflection on the "Golden Rice" trial. *Chinese Medical Ethics*. 2013, 26: 14-16
- Mandave A, Pace C, Campbell B, et al. The quality of informed consent: mapping the landscape. A review of empirical data from developing and developed countries. *J Med Ethics*. 2012, 38: 356-365
- Hill Z, Tawiah-Agyeman C, Oder-Danso S et al. Informed consent in Ghana: what do participants really understand? *J Med Ethics* 2008, 34: 48-53
- Ma Y, Xin B, Wang N et al. The Investigation Study for Understanding of Informed Consent on Individual Sample Collection in Medical Research. *Medicine and Philosophy* 2012, 33: 28-30
- Meng R, Zhai Y, Chen S, et al. Investigation on Current Condition of Medical Ethics Consciousness and its Enlightenment in Epidemiological Research. *Chinese Medical Ethics* 2012, 25: 828-829
- Meng R, Zhai Y, Chen S, et al. Differences on ethical consciousness issues between the Chinese Journal of Epidemiology and the American Journal of Epidemiology. *Chinese Medical Ethics* 2012, 33: 106-110.

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