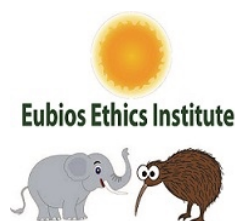


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World Bioethics Day 2016 Issue

This issue includes 8 papers in a celebration of diversity and global bioethics. There is a mixture of philosophical analysis, classroom teaching strategies and student surveys, policy analysis, historical commentary, and cross-disciplinary analysis of bioethics issues from various countries. Promotion of a good-life (Eubios) for all beings is a critical element for healthy bioethics discourse, that we share with the spirit of World Bioethics Day which this issue celebrates thanks to the suggestion of Irina Pollard. This issue is published and the editorial is written on the 19 October and AUSN also celebrated with an active debate and dialogue from Asia, America, Europe and Africa.

The Asian Bioethics Association (ABA) and local hosts, the Indonesian National Bioethics Commission and UGM in Yogyakarta, Indonesia, will soon hold ABC17 (14-17 November 2016) to continue this discussion and education of bioethics. AUSN and Eubios Ethics Institute are also co-organizing with others a number of Bioethics Conferences trainings in the coming 7 weeks all around Asia and the Pacific, so please join physically or by skype.

- Darryl Macer



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Cross Cultural Perspectives on Dignity, Bioethics, and Human Rights: A Reflection on World Bioethics Day

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Part 1: Introductory Background

The term bioethics prompts us to think 'biology' and 'ethics' emphasizing the importance of science and its applications as they relate to our modern technologically-based societies. Decisions about the responsible use (or misuse) of science's capabilities embrace a diversity of matters such as the environment, human health, society and international policy – all challenging population growth, economic activity and conflict resolution including warfare. Clearly, contemporary science and its possible technological applications occur within the contexts of societies which may have generated differing philosophies, beliefs and ethical values structures. Therefore, to resolve differing perspectives on a diversity of significant issues and to develop global principles underpinning sustainable and worldwide decision making, we need to cover contemporary attention as characterized in, for example, anthropology, sociology, biology, medicine, religion, psychology, philosophy, environmental science and economics. Since ethical values cannot be separated from biological facts we are increasingly in need of a sustainable international ethic involving the survival of the total ecosystem.

In the above context, the UNESCO Chair in Bioethics (Haifa) has announced a **World Bioethics Day** to be celebrated globally for the first time on the 19th October, 2016. The theme of this year's celebration is 'Human Rights and Human Dignity' (article 3 of the Universal Declaration of Bioethics and Human rights). The present in human history may indeed be the most appropriate time to enforce a complete rethink of everything in order to build a functional future interlocking new and sustainable models of existence.

The indiscriminate use, abuse and misunderstanding of science's valuable technological developments are, beyond doubt, a matter of ethical concern and collective responsibility. Biological education, while consistent with new knowledge, ought also to be relevant to real-life experiences within sociocultural and ethical contexts. Bioscience ethics¹ provides a

source of information that bridges the gap between applied science and applied ethics. An all-encompassing interpretation of bioethics, the knowledge of which would promote both human survival and improvement of the human condition is in need of urgent review.

Reworking the Future for Following Generations

It is reasonable to postulate that for the hunter-gatherer a deepening understanding of the wisdom and beauty of Nature may have played the central role in the evolution of ethical thought. It may be useful to remind ourselves that 'aesthetics' has its root in the Greek word '*aisthetes*' meaning 'one who perceives', illustrating the wisdom of integrating science, ethics and art with Nature. Holistic ethics (also sometime called ecocentric ethics where the entire ecosphere is considered) was practised in ancient traditions and has survived in several forms as, for example, the Dreamtime of the Australian Aboriginal people. Recorded history gave us more insight into our recent evolution.

Much is made of the Sumerians of Mesopotamia (the ancient country between the Tigris and Euphrates rivers, now Iraq) who, in about 3000 BCE², left behind a vast legacy of 'firsts' inscribed on clay tablets in cuneiform script. Theirs was the first recorded example of a palace-driven urban society co-operative with government. The Sumerian legacy also included an early record of ethical thought. The ethical concept had to do with restoring justice and freedom to the citizens of Lagash, a Sumerian city-state. But human civilization had been developing for several millennia before the written record began, so that the evolution of premonitions of human ethical thought on topics such as truth, justice, freedom, mercy and compassion began long before their written record. Relationships between Nature, science, medicine and ethics continued to occupy our ancestors till the present day reinforcing the fact that ethics and morality are natural phenomena that evolved from an evolutionary scheme shaping social behaviour maintained by deeply interlocking brain processes. Now, more than ever before, the time has come when our accumulated intellectual knowledge and extraordinary expertise is asserting *Homo sapience* to advance a value-based ethics in modern terms. The following summarizes how my University has responded to this need.

Education – History's Newest Revolution

There is an increasing employer demand for their employees to be equipped with the knowledge and skills they need to be responsible global citizens. Macquarie University has responded to this need by means of its Global Leadership Program (GLP). Macquarie's Global Leadership Program offers students the opportunity to undertake a challenging extra-curricular program designed to build leadership ability, international awareness, cross-cultural

¹ Irina Pollard, *Bioscience Ethics*, Cambridge University Press 2009.

² BCE – Before the Common Era. The reader is also welcome to substitute the equivalency BC.

understanding and professional skills. The GLP is the first program of its kind in Australia in which over 2,800 undergraduate, postgraduate and study abroad / exchange students are actively enrolled. The GLP project convenors understanding of 'Global' embraces the following:

- Cultural literacy and cross-cultural competence.
 - Global perspectives and outlooks.
 - Global issues including legal, political, economic, social, cultural and ethical.
- Human dignity and human rights.
 - Diversity & multiculturalism.
 - Indigenous culture and rights.
 - Environment and sustainability.
 - Global citizenship including ethical behaviour and social responsibility.

Apart from the requirements as listed above there is also a persistent and targeted call to cover the prevailing shortages of publicly accessible programs that challenge the knowledge gap between newly acquired technological information and bioethical arbitration. Dr Irina Pollard is the invited convenor of the project designed to cover the bioscience ethical subdivision of Macquarie's GLP program. The following reveals her basic contributions to ethics education and reflect on similarity as interrelated to possible contributions as recently identified for World Bioethics Day to be celebrated for the first time on 19th October 2016.

The ethics Colloquium reflects upon the heritability of ethics and its socio-biological implications and investigates lifestyle and reproductive health, fertility and the assisted reproductive technologies (ART). The colloquium also considers the evolution of the human brain and socio-ethical impacts on political rights, international conflict and peace initiatives. Through ethical playoffs, role plays and international case studies students are invited to explore the ethical dilemmas arising from the intersection of science, culture and technology.

Part 2: Bioscience Ethics – International Perspectives on Human Reproductive Biology

Technologies, all by-products of science, have redefined how we live, work, fight, relax and communicate with one another. Bioscience ethics is an unencumbered secular discipline that facilitates free and accurate information transfer from applied science to applied bioethics. Since the 1990s, bioscience ethics has become an internationally recognized discipline interfacing science and bioethics within professional perspectives such as medical, legal, bioengineering and economics (<http://www.bioscience-bioethics.org/>). In the final analysis, bioscience ethics is a transdisciplinary subject whose dimensions are reflected in the emerging frontiers of science and ethics that enhance biological understanding and promote adaptive harmony with changing technology. Flexible open-ended engagement by whatever means are potent forces for building bridges that generate positive change globally.

Colloquium Outline

Part 1 is on maintaining health and wellbeing; the heritability of ethics; change from conception to death; sociobiological implications.

Part 2: reproductive health; lifestyle and environment; assisted reproduction and epigenetics.

Part 3: the evolution of the human brain; automatic survival functions; transgenerational effects of stress; the ecology of violence and warfare; conclude with science ethics education i.e., biological rights and political rights continuum; risk management – the precautionary principle.

Delivery Mode

The Colloquium is modelled as interactive workshops that encourage students to discuss, debate, analyse and critically engage with the topic. Convenors are encouraged to create an open forum where students feel comfortable asking questions, contributing their perspectives and participating in group activities. The following group activities are included to encourage participation:

- Key discussion questions.
- Debates
- Role plays
- Simulations
- Small group activities - for example a real or hypothetical case study that students consider from multiple viewpoints.
- Facilitated self-reflection.
- Framing the workshop according to questions/interest students have about the topic.

Student Learning Objective and Outcomes

- Able to critically analyse across disciplines, cultures and diverse environments.
- Able to communicate ideas and be a force for positive social change.
- Able to pay attention and learn from others.
- Able to produce coherent, logical and ethically sound arguments.
- Able to work independently and cooperatively.
- Able to extract key bioethical issues from the scientific literature, presentations and group communications.
- Acquire a wide-ranging understanding of major ethical issues posed by particular assisted reproductive technological advances and their applications.

In summary

It is expected that the above objectives and outcomes will increase biological knowledge which, in turn, will strengthen ethical interest across divergent cultures and environments.

Examples of Possible GLP Topics for Discussion

- Earth – our common home – is increasingly being destroyed thanks to human activity.
- People most affected from climate change will be those living in the Asia-Pacific region

- From anthropocentrism to biocentrism.
- The early days of Artificial Reproductive Technology (ART) was an ethical nightmare.
- What is the role of doctors and healthcare providers in safeguarding the unborn child's health?
- What are the rights of a fetus?
- The patient was a married woman whose husband was infertile. Without seeking consent of either husband or wife, the doctor inseminated her with the sperm of one of his medical students.
- Interdependence; cycling of resources; adaptation; succession and justice are the driving determinants of psychosocial health.
- Bioscience ethics is dedicated to fostering public awareness and understanding of bioethical issues and to exploring solutions to bioethical challenges.
- Group reflection on how the colloquium content is useful / relevant to becoming a Global Citizen.

Reflect on a picture: <http://www.9to5hdwallpapers.com/wp-content/uploads/2012/03/cute-little-baby-hd-wallpaper.jpg>

EJAIB & I

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In this Letter to the Editor, I would like to commend the *Eubios Journal of Asian and International Bioethics* (EJAIB) for the characteristics of their journal publications that are not found in other journals. In submitting many manuscripts to the *EJAIB* over the past two decades, I have come to appreciate the distinct and invaluable policies of this journal concerning paper acceptance and publication. Between 1995 and 2016, the *EJAIB* has kindly published as many as 25 papers and 8 case studies that I solely or jointly wrote. In addition, one paper was also included in one of the books published by the Eubios Ethics Institute. This means that I have published roughly a third of all my academic papers in English in the *EJAIB*.

The themes of these papers are quite diverse and include topics such as the ideal forms of medical ethics education, problems concerning informed consent in Japan, descriptive studies of ethical dilemmas in clinical settings, medical futility as an essential concept, appropriate medical care for patients in a persistent vegetative state, unknowability about facts and the need for humility, cultural issues in self-determination and proposals of new ethical principles, implications of the UNESCO Declaration of Bioethics and Human Rights, arguments on the validity of secular ethical positions relative to religious perspectives, pros and cons of capital punishment and difficulties in making definite conclusions, an ethical analysis of commercial films concerning Hansen's disease and capital punishment, the impossibility of

death with dignity in present-day Japan, confidentiality and the duty to warn others when caring for a patient with HIV, proposal of medical ethics education using the Analects, issues concerning how to deal with an incompetent patient's refusal of medical treatment, disagreement among family members about life-sustaining treatments, compulsory interventions for psychiatric patients, urgent unproven interventions for pediatric patients, a patient's ability to pay healthcare costs, and assisted reproductive technology and its resulting changes in family dynamics.

I have come to acknowledge fully that the *EJAIB* as a journal is quite broad-minded, truly global, and progressive. Moreover, its policies are highly distinctive. For example, the *EJAIB* was the first of many bioethics journals to begin publishing online for open access—an exceptional feat at the time. The *EJAIB* has accepted papers pertaining to diverse themes in the field of bioethics and has not excluded papers that other journals are likely to judge as inappropriate, such as my paper on capital punishment. Papers on a wide array of topics are accepted, and not just those written about trendy topics of that particular era. Another laudable policy is that the journal does not stick to mere formalities and has not gotten caught up in the so-called academic customs, as exemplified by my case study on urgent unproven interventions on pediatric patient published in the *EJAIB*, which was written in a very unconventional manner.

In addition, authors can state honestly and without hesitation that “I do not know” or “We have no conclusions thus far” in the Conclusions section of a paper. Other journals would not allow this ambiguity or admittance that conclusions simply cannot be drawn on some issues in the real world. An example of this would be our recent paper about somatic support of brain-dead pregnant women and childbirth, which concluded that conclusions could not be made on many issues. The *EJAIB* also allows authors to express rather controversial positions, both freely and frankly. For example, my coauthors and I were able to publish a paper concerning an incompetent patient's refusal of life-saving treatment, allowing us to express the opinion that sometimes an incompetent patient's refusal should still be respected, for the reasons of emotional capacity rather than rationality.

Finally, the *EJAIB* is very generous and helpful to non-English speaking authors, and does not reject a manuscript solely because of less-than-perfect English expressions. Other journals sometimes require multiple rounds of English proof-reading, even if the first version was appropriately proofread by professional native English speakers. As a Japanese author who constantly struggles with English, I greatly appreciate the editors' tolerance of linguistic issues, and would go so far as to say that this encourages and promotes the global or international perspectives of the journal.

Thank you, Darryl. I hope to continue sending my manuscripts to the *EJAIB*.

Seven Sexual Revolutions in History: Destination - Successful Failure

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Introduction

Necessity is laid upon humanity to step back and to trace the origin of sexual revolutions and its proliferation down the memory lane in human history. This is a survival need. As the sexual revolution proliferates the population level also dips. Further the total fertility rate (TFR) of human population is declining. Will human sex revolution enhance the chances of human survival as a population or endanger it?

The present study is divided in to three parts: (i) sex revolution in the very ancient historical past (ii) in the very recent past and (iii) in the near future. In order to trace sex revolution to the very ancient past it is needed to identify a non-religious and trustworthy ancient text. Such a text has been identified. The present trends in sex revolution have been traced by analysing the published results of sociological surveys among American society. The future trends have been assessed by making predictions based on the recent advances in stem cell assisted reproductive technology. The study also focuses on the question: "Are morals, men, sex, and God necessary for human survival as a species?" Of these four issues two issues - morality and sexuality - are considered as marks of Humans for further consideration.

The Origin of Sexuality

For any scientist who wants to trace the origin of human sexuality and sex revolution it is an impossible task since there is no cultural fossil to documents it. Alternately one has to turn to ancient recorded texts (now known as scriptures), either to Vedic or to The Book of Genesis.

Affirmative consent that the Book of Genesis (Gen.) is a universally valid non-religious reliable document is found in the works of Dr. S. Radhakrishnan who was a profound Hindu proponent and a world renowned philosopher. Servapalli Dr. S. Radhakrishnan was also the past President of India. His understanding of the opening chapters of Genesis is quite remarkable. He claimed that that the early chapters are a common heritage to all humanity. He wrote correctly "*The Jewish Bible does not begin with the Jews. It starts with the story of Adam, which in Hebrew means 'man', adomi. The book of Genesis says: 'This is the book of the generations of man'. It does not speak of the Levite, the priest, or the Jews but of men. The children of earth are viewed as one family. They have one ancestor who is the father of all*" (Radhakrishnan, 1968

p. 36). Judaism and other world religions including Christianity were not practised at this stage in history! Hence the Book of Genesis is a reliable non religious document.

Fertility – Common To All Humans

The Book of Genesis contains the very first fertility blessing on humankind. And God blessed them (male and female), and God said unto them, "*Be fruitful, and multiply, and replenish the earth, and subdue it*" (Gen. 1: 28). Fertility is the ability to reproduce i.e. to "be fruitful, and multiply, and replenish". This is a threefold unconditional blessing which is effective to all humanity regardless of religion. It is very hard to make it inoperative. It works seamlessly well in a God centric society. In human beings this blessing operates through sexual reproduction since human beings are sexual beings. Therefore sex occupies and plays a dominant role

Fecundity

Fecundity is the number of eggs a female can produce in a reproductive season. Some fishes have two reproductive seasons per year while others have one. A very big fish can produce millions and millions of eggs. Since the process of fertilization is external many of the eggs and young ones will be eaten by larger predators. In the case of human beings fertilization is internal and a single fertile egg is produced per monthly cycle throughout the year. Dogs can have sexual intercourse only during the reproductive season, one season per year. But human beings can have sex throughout the year but not throughout the life time. There is precisely defined "childbearing years" for a human female.

Total Fertility Rate

The term "Total Fertility Rate" refers to the number of children a woman can deliver in her married life time. Total fertility rate (TFR) is the average number of children that is likely to be born per a given woman of a country when all women live up to the end of their childbearing years and bore children according to a given fertility rate at each age. TFR is therefore a direct measure of the degree of fertility of a woman. It differs from the crude birth rate which refers to births per woman. TFR is a critical factor in ensuring the stability of a human population.

A country must ensure that a woman should give birth to at least two or three children to keep the population above the critical replacement level: one child to replace the death of a person and one to keep the *status quo* and the third to keep the level well above the critical replacement level. Human technology can interfere and affect the threefold fertility blessing: by the production of condoms and contraceptive devices to arrest the process of "be fruitful"; to legalize abortion to arrest the ability to "multiply"; and to introduce socially and culturally detrimental norms and practices that will adversely affect the TFR.

Factors Affecting TFR

There are many factors that affect TFR. They fall under social cultural legal and political frame work. These factors are: sexual revolution; abortion, after birth abortion; use of condoms/contraceptives; same sex marriages and legalizing them; cohabitation and live-in-relationship, cryopreservation of sperm; childfree life by choice after marriage; single mothers by choice; eating genetically modified food and eating fruits cultivated with methyl iodide which is a reproductive endocrine disrupter. Let us take sexual revolutions and its associated factors for further discussion.

The Very Ancient Sexual Revolution

In ancient historical past there were two great and powerful political rulers: the Pharaoh the king of Egypt (Gen. 12) and Abimelek the king of Gerar (Gen. 20). The culture of these two neighbouring countries has relevance for the present study. These two kings practiced a culture of treating ALL beautiful but unmarried women as their own property. If the very beautiful woman is married then they make the woman unmarried by killing the husband. There were no dignity of human life and the rights of a woman. This was their national policy of unlawful rule of their law. Two issues arise from the unethical practice. (i) Is sexual revolution linked with a notion of not nurturing the "fear of God"? (ii) Was there a sexual revolution in these monarchical regimes?

Fear of God and sexual revolution

Abraham had a fateful encounter with both Pharaoh the king of Egypt (Gen. 12) and Abimelek the king of Gerar. His life was in very great danger because of his very beautiful wife and because of the practice of killing the husband to release the beautiful lady. Abraham found that there was absolutely no fear of God in the kingdom of Gerar/in their eyes (Gen. 20: 11). That indeed sex ethics and fear of God are inversely related is strongly supported by sociological surveys conducted during the present 21st century. Secondly it is indeed sex revolution to deprive the rights and dignity of womanhood to consider the woman as a mere property to be acquired.

The Very First, Second & the Third sexual revolutions

There were three sexual revolutions in the Genesis account. The first sexual revolution occurred in the line of brutal Cain, the son of Eve and Lamech who was the head of the family of inventors (Gen. 4). Lamech took two wives and murdered those who opposed his new ethics. He very boldly broke the century old cultural tradition of considering marriage as the union between one man and one woman. His new culture became widely accepted practice that Abraham's father married two wives. This is the impact of the very first sexual revolution. Even Abraham and King David were victims of the first sexual revolution.

2nd Sexual Revolution

The second sexual revolution is that of high sex culture practiced in the kingdoms of Egypt and Garar (Gen. 12 to 20). Details of the 2nd sex revolution have been given in an earlier section.

3rd Sexual Revolution

In the ancient past there were two kingdoms - Sodom and Gomorrah (Gen 14: 8). The third sexual revolution took place in these kingdoms where the citizens practiced MSM – i.e. men having sex with men (Gen. 18 -19). What about the women? The men of these two kingdoms had legal sanctions to practice 'gayism'. Hence the kingdoms can be termed as termed as "Gaydoms". There may have been many other types of legal freedom including religious freedom but not for the practice of heterosexual autonomy. The cost and consequences of adopting a culture of MSM were immense. There was a very serious environmental destruction and these two kingdoms were totally wiped out (Azariah, 2015 a).

Fourth sexual revolution (1920)

There were additional three sexual revolutions since the 1920s (Huber, 2015). The year 1920 marked the initiation of the fourth "sexual revolution." Party songs carried the message of sexual permissiveness of the flapper generation. There were pop songs with lines like: "Too Many Parties, Too Many Pals" and "She isn't like her mother, and yet she might have been, If it hadn't been for petting parties, cigarettes and gin"

This indicated the beginnings of sexual pulse of the day. Even though the carefree lifestyle of the 1920s ushered in a conservative backlash against habits that were deemed harmful to the family and society all the expectations about sex were reserved for marriage alone (Huber, 2015).

The seed of fourth "sexual revolution." took time for germination but for an unknown zoology professor at Indiana University who wrote, in 1948, on the topic of "*Sexual Behaviour and the Human Male*". His tickling report put an end to the conventional understanding of sex (Huber, 2015). Alfred Kinsey followed the above argument and concluded that "most men and women are not monogamous, that humans are sexual (and sexually responsive) from birth, that 10 percent of men are homosexual, that bestiality is fairly common behaviour and that "celibacy, delayed marriage and asceticism" are "cultural perversions." Huber (2015) commented on the sexual climate of that day by pointing out the view of Kinsey's colleague Paul Gebhard: "It didn't much matter what you did sexually as long as it didn't hurt anyone else and it made you and your partner happy." Although the Kinsey report became a bestseller traditional conservatives held the view that sex belonged within marriage. Thus Kinsey's views began to work to erode cultural expectations surrounding sex. Thus the floodgates for the 2nd sex revolution were slowly opened.

Fifth Sexual Revolution and the Growth of Sex Education

The year 1960 marked the birth of the fifth “sexual revolution”. The birth of full-fledged pornography in 1970 led to the remark that the year 1970 was the golden year of pornography and 1970s accelerated the acceptability of premarital sex as morally ‘right’. The availability of the contraceptive Pill and abortion to cover the obvious effects of sex offered men and women sexual freedom without the consequences of conception. But there were breaches in other areas of moral domain. Births outside of legal marriage were doubled between 1960 and 1970. The incidence of Sexually Transmitted Infectious Diseases in young adults was increased by 165 percent between 1967 and 1971 (Huber 2015). Thus it opened the floodgates for sex education.

Sixth Sexual Revolution

The sixth sexual revolution began to take roots in 1980s. It relates to marked changes in sexual orientation and the redefinition of marriage. In the past millennium, traditional marriage was defined as the union between a male and a female, The American DOMA (Defence of Marriage Act) endorsed it. This union is child centric producing biological parents. When the number of gay and lesbians increased they were not covered by DOMA. The word “marriage” needed to be redefined as the union between two persons or people regardless of sex. It should be noted that the partners in gays and lesbians relationship are indeed human persons and hence their partnership includes shades of human rights issues. Nevertheless it should be emphasized that this same sex union is essentially a child-adoption-centric (foster children) relationship and incapable of producing biological parents. In the case of lesbians a frozen sperm or a male sperm donor is necessary (Azariah, 2015 b).

It all started as (i) same sex relationship (1980s) which was upgraded as (ii) same sex marriage (2015). Currently attempts are being made to achieve (iii) same sex reproduction by deriving a sperm and fertile human egg from the stem cells (2030?). Derivation of a woman’s egg appears to be a very strong limiting factor. Necessity will arise in a later day when and if stem cell technology overcomes this obstacle of not being able to derive a fertile human egg from one’s own stem cell to re-define the word “marriage”.

Seventh Sex Revolution

The seventh sex revolution is yet to be born. But the foundations have been laid so as to cater to the needs of same sex reproduction. A new film “*The Baby Formula*” imagines two lesbians conceiving (Same-sex reproduction) with sperm derived from each other’s stem cells – and the science may not be far-fetched. This new film was directed by Ms. Alison Reid with lesbian actors Megan Fahlenbock and actor Angela Vint.

The current and immediate issues are redefinition of marriage, marriage equality and legalizing of same sex

marriage. Now the conversation which runs like “my husband she has gone to work” and “my wife he is cooking...” will be history. But in future what will be the problem(s)? It is hard to predict. Tomorrow’s issue will be “Will women one day father children?”³

Cumulative impact of Sexual Revolutions

Laumann *et al* (1994) reported on the number of sex partners of American males and females have had since the age of 18. Their report revealed that “3% of men have had zero sexual partners since the age of 18, 20% have had 1 partner, 21% have had 2-4 partners, 23% have had 5-10 partners, 16% have had 11-20 partners, and 17% have had 21 or more partners.” There was a significant variation in the number of sex partners between males and females in the age group of 30-44 years. Mosher *et al* (2005) reported that males had on an average of 6-8 female sexual partners in their lifetime whereas females had 4 male sexual partners in their lifetime. The data represents a normal distribution curve. Similarly data are available for females. “3% of women have had zero sexual partners since the age of 18, 31% have had 1 partner, 36% have had 2-4 partners, 20% have had 5-10 partners, 6% have had 11-20 partners, and 3% have had 21 or more partners. 20% of American men and 31% of American women have had one sex partner in their lifetime”.

Two inferences can be made out of the above data: (i) men and women were not satisfied with their (married?) sex partners and (ii) they sought sexual pleasures outside of their marriage which means that they cheated on their spouses.

1980s Health Impacts - AIDS Crisis

Beginning with 1980s the world was led into a deadly AIDS crisis. Sex education in the schools was an imminent need of the hour. Organizations like Sexuality Information and Education Council of the United States (SIECUS) developed sex curricula in teacher-training programs which did not emphasise the debarring premarital sex and promiscuity in teens and young adults. A paradigm shift in sex prevailed in academic teaching advocating that it is normal for schoolchildren to do experimentations in sex. Based on the Alfred Kinsey’s report a new sex revolution was introduced under a brand new name of ‘safe sex’ which heavily rested on the use of condoms.

Injection Drug Users and HIV

HIV infection is generally associated with socio-cultural factors such as homosexual behaviour and Injection Drug Users (IDUs). The town Austin, Indiana is a socially conservative, largely rural region just north of the Kentucky border. But they are IDUs and use needles over 300 times. A drug addict, a 45-year-old woman tested positive for HIV, one of nearly 150 cases in a small population of 4,200 people. Fear gripped her when she learned the unforgiving

³ This issue was in news media like *The Globe* and *The Mail* - 19.06.09.

consequences of HIV infection. She is stigmatised to start antiretroviral therapy because she does not want to be spotted entering the clinic on Main Street (Goodnough, 2015). There was a severe outbreak of HIV and hepatitis due to a surge in heroin use in states including Indiana, Kentucky and West Virginia (Hulse, 2015).

Condom-centric culture

Strong emphasis was placed on the avoidance of conception and the prevention of AIDS. In sex education students were taught sexual risk avoidance (SRA) rather than sexual abstinence and moderation in sexual activities in teens. Condom-centric – risk-reduction programs exploded and the age of first sex experience was lowered to 16-17 years of age. With the advent of new found high culture of sex without restrictions teens began to spend more time with sex and less time with their academic studies. A young girl came home and told her mother “we were taught what not to do; where not to do; when not to do; and how not to do!” Such a “progressive” free sex culture came with a heavy price tag in terms of human fertility loss and adverse impacts on the reproductive health of the woman.

Use of condoms/contraceptives

Data collected by the General Social Survey of American population provide interesting revelation in the pattern of sexual activity in USA. Stephens-Davidowitz, (2015) found an interesting contradiction between the heterosexual men aged 18 and above and heterosexual woman on the performance of sex acts and the usage of condoms. Men confessed that they do on an average of 63 sex acts per year, 23 percent of them used a condom which may reveal that more than 1.6 billion heterosexual condom usage per year. On the other hand heterosexual women say they are engaged in an average 55 sex acts per year, using a condom in 16 percent of them which adds up to about 1.1 billion heterosexual condom users per year. There is a slip in the data and Stephens-Davidowitz (2015) asks the question “Who is telling the truth, men or women? Neither”. In USA, moreover, just about 600 million condoms are sold every year. It is predicted that the condom market may reach well over 700 million.

What about India? An internet search yielded no data on the number of condoms and contraceptives sold per year. Nevertheless a rough estimate can be made. In a city like Chennai there are 100,000 sex-workers who are expected to entertain at least three customers per day. All of them practice safe sex and use condoms. This works out to 300,000 sex acts per day. The rest can be calculated. It seems certain that sex is one single dominant act humans do.

Sexual revolutions ushered in the necessity to introduce sex education in educational systems and the free distribution of condoms. But condoms sometimes fail to prevent conception. Unwanted pregnancies are eliminated. Liberal views in family planning favour abortion. Therefore abortion clinics

were opened which polarized the society into two groups: the pro-life activist and the pro-choice groups. In USA, from 1973 to 2015, there were about 57.5 million (m) abortions and in China 336 m due to one child policy. In India, female foeticide amounts to 24 m or more. These figures dwarf the number killed during World War 1. In WW1 about 1.5 m Armenians were killed. Hitler killed 17 m and Joseph Stalin killed 23 m only. These killings affect TFR adversely.

Sex Revolution Cultural Pollutant

Ms. Mary Eberstadt has published a ground-breaking book entitled “*Adam and Eve After the Pill: Paradoxes of the Sexual Revolution*” (March, 2012) on the widespread discontent with regard to the newly found sexual freedom. She brings to light that both secular and religious leaders are of the opinion that “the sexual revolution is one of the most important milestones in human history. Perhaps nothing has changed life for so many, so fast, as the severing of sex and procreation. But what has been the result?” Eberstadt, in her book, “makes a strong case that contraception is the technological engine of negative changes in the way men and women have come to live their sexuality and their relationships in general” (Migeon, 2015).

r & k-factors

The book, “*The Population Bomb*” authored by Paul Ehrlich induced an unfounded technological fear in the minds of politicians that uncontrolled population explosion will result in the imbalance between natural resource availability and per capita utilization. In the study of population growth two factors are important: the *r* – factor and the *k*-factor. The *r* – factor refers to the “reproductive potential” of a young growing population which is birth (*b*) minus death (*d*) or $(b - d) = r$ and the *k*-factor which represents a stable population that has reached a stability with the carrying capacity of the environment wherein $(b - d) = 0$. It is a mature stable population. The carrying capacity is a limiting factor in animal population. Strangely human population growth does not follow these limiting factors. Human population growth is a density independent growth. Human populations multiply in spite of limiting factors. The most important limiting factor is the reproductive health of the woman and her functioning womb.

Contraceptive Chemical pollution

The chemical pollution that adversely affects reproductive health of a woman is the widespread use of hormonal contraceptives. Ms. Grigg-Spall is the author of the book “*Sweetening the Pill*”. She documents negative impacts of hormonal disruptive contraceptives. In adults the “symptoms ranged from significant increase in breast size and severe pain, mouth ulcers, loss of sex drive, significant increase in appetite leading to weight gain, monthly bouts of thrush, depression, fits of rage, fatigue, suicidal thoughts and loss of focus and motivation.” In teenage young adults the “reproductive systems are shut down before they are fully developed.”

These hormonal contraceptives suppress ovulation and menstruation. Evidences are mounting that hormonal contraceptives are directly linked to the reproductive health disorders of women. Moreover, the habit of morning a pill causes every woman to “experience, over time, impaired physical and mental health”. Besides there is other “extensive, direct effects brought on by various formulations: dehydration of the body, vitamin deficiency, suppression of the adrenal glands, and reduction of testosterone. These disruptions can result in increased allergies, low energy, poor sleeping patterns, increased blood pressure and stress, higher risk of heart attack, and low libido” (Migeon, 2015).

On the other hand fertility awareness based methods (FABMs) are preferable since they relieve women of the pollution to her body. A personal testimony of Grigg-Spall makes a woman a fertile woman: “In the few months I took off the pill I felt lighter. A rush of positive emotions let me feel happiness, excitement and enthusiasm”.

Landmark Years

The following years –1920, 1960 and 1980s are the important years that changed the course of human sex in history. In the 1970s and 1980s, Paul Ehrlich’s book, *The Population Bomb*, successfully galvanized the general fear that population growth meant doom for our planet. It triggered international campaigns and policies aimed at controlling birth rates worldwide. But, while trying to save the earth with implementation of now disproven population policies and theories, we have endangered one key species: humans; specifically, women.

Women’s health has been put at risk by the widespread use of contraceptives and, for many women their own reproductive ecosystem has fallen apart to uncoordinated pieces and even become hostile to motherhood. Two contemporary authors, Holly Grigg-Spall and Mary Eberstadt are from radically opposed viewpoints on ethics and politics, But each put forward their case effectively that hormonal contraceptives have much to do with the endangerment of women and her reproductive health.

Eberstadt, in her book *Adam and Eve after the Pill*, made a strong case that contraception is the technological engine of negative changes in the way men and women have come to live their sexuality and their relationships in general. She has described “the social evidence we have witnessed in the past 50 years of broad use of these methods: an increase in pre-marital sex and cohabitation, of extra-marital affairs, of divorce, and a general acceptance of sexual behaviours previously considered harmful to society”. She added that “modern contraception may even be the central fact of our time: it is hard to think of any other whose demographic, social, behavioural, and personal fallout has been as profound.”

The relationship between a woman and her spouse/partner, which until now was a primary base for a stable “reproductive-ecosystem,” is not going well. While, according to Eberstadt, there is ample

evidence that “married, monogamous people are most likely to be happy,” fewer find themselves in that situation. The number of divorced or separated women has gone from about 6 percent in 1950 to 15 percent today, and of never married from 17 percent to 29 percent. This trend comes at a high price for women, who end up raising children on their own and having to fend for themselves on one income.

Single mothers by choice

A penetrating question was raised by Hampikian (2012) “Men, Who Needs Them?” or does mankind really need men to produce babies? The answer is a “No” for the following reasons.

(i) For procreation women are essential and are self sufficient; while men are not.

(ii) “If a woman wants to have a baby without a man, she just needs to secure sperm (fresh or frozen) from a donor (living or dead). The only technology the self-impregnating woman needs is a straw or turkey baster, and the basic technique hasn’t changed much since Talmudic scholars debated the religious implications of insemination without sex in the fifth century. If all the men on earth died tonight, the species could continue on frozen sperm. If the women disappear, it’s extinction”.

(iii) Cloning totally eliminates both sex (inter course) and the importance of man in procreations. (iv) Human sperms can be ‘created’ from the stem cells while the human egg cell cannot be manufactured. More importantly nothing can be done without a woman’s (human) womb. Finally due to some selective catastrophe if all the men are eliminated from on earth then human race can continue by self impregnation by a woman with frozen sperms but if the womb of a woman disappears then it is nothing but extinction of a powerful and intelligent species.

Fatherless broken Homes

New data were published by the Family Research Council (FRC). The Index of Belonging and Rejection released by them “revealed a dismaying statistic about the state of American families: 55 percent of 15-to-17-year-olds in America do not live in intact families” (Ford 2014). It is statistically sad to note that “more than 40% of all children are born out of wedlock and one in three children live in single-parent homes. If Americans are concerned about the next generation, it’s time to strengthen marriage.” The ill effects of a unstable society built on a foundation of declining strength of a traditional marriage was reiterated by the American President when he said “We know the statistics—that children who grow up without a father are five times more likely to live in poverty and commit crime; nine times more likely to drop out of schools and twenty times more likely to end up in prison. They are more likely to have behavioural problems, or run away from home, or become teenage parents themselves. And the foundations of our community are weaker because of it” (Ford, 2014). It is a common knowledge that married parents in an intact family have a edifying influence on the lives of children from low-income

households since stable marriages in intact families reduced childhood poverty by 82%. The research study clearly showed that “children who live in single-parent homes— or communities where the majority of homes are headed by single parents— have a significant disadvantage in moving up the income scale.”

Morals – 2nd Mark of Humanity

Human beings are moral and spiritual beings too. Human morality is the moral- spiritual framework that sustains the human ability to distinguish the ‘right’ from (and) the ‘wrong’ as well as the good from the evil. The origin of morality is not an easy topic for discussion. Those who are spiritually minded will link it with the creation of humankind in the image of God since God is the moral person. Unlike the believers in God the ‘non-believers’ may find it difficult to ascertain that morality is an evolutionary by-product since there is no intermediary cultural fossil in all the plant and animal kingdoms to support the worldview of evolutionary biology that there are transitional animal fossils which are ethical in nature. It does not mean then that a non believer or a secularist or a rationalist or an evolutionist is immoral. No one can say that an evolutionist can’t be a morally upright person. With or without God a person can be morally a good person. An atheist can say that God is not necessary in his/her life to lead a morally good life. But the ground truth paints a different story. Barna Research Group conducted a survey on the attitude of both spiritually minded persons (Christians & Other Faiths) and on non believers (Agnostics & Atheists) towards the acceptance of seven moral issues as ‘morally acceptable behaviours’. Surprisingly the non believers (Agnostics & Atheists) were readily accepted these seven moral issues (like abortion, cohabitation without marriage and nudity) as ‘morally acceptable behaviours’. Details are discussed below.

Moral Development

There are just two streams of thought on moral development: (i) the secular (rationalist /evolutionist and non-believers) and (ii) the religious (Hindu, Christian and Islam). A person’s moral development is linked with country of birth, religious faith of the parents or partners and upbringing of the child. In a child’s bodily development stages sex hormones play a significant role in the sexual awakening of a child. The internet has brought the various contours of human sexuality at the moral door steps of a developing mind. Pornography is one such contours of human sexuality – a corrupted form of sex. In the developed and Christian influenced western nations a child, as early as nine years of age, is exposed to such corrupted sex by a simple press of a button of a hand set. Therefore in this study an attempt has been made to trace the changes in the perception of sex ethics from a moral viewpoint. This has been done by studying human-sex-history of the recent past. Useful and large amount of data are available on the public domain. The present study has used these survey

statistical data which have been recently published on the mindset of Christians, other faith groups, agnostics and atheists towards human sex and sexuality in USA.

Happiness Gap: Between Pornography and Religious Mindset

Do people with religious mindset view pornography? Yes! They do! The Austin Institute for “The Study of Family and Culture” carried out a study on pornography and religious affiliations. The study respondents were Christians belonging to mainline churches of Protestants and Catholics with 4 to 5 subsets in them. The survey assessed the percent of respondents who viewed pornographic materials a week before the survey (Patterson and Prince, 2012).

The research team published the results with graphical representation. Following is a summary of their results. Percentage values are given in parenthesis. The results showed that American men in both the study groups view pornography more than women. American Christianity is steadily losing its moral grounds. According to this study pornography has come to stay deeply rooted in American soil. The data are summarized below.

Evangelical Protestants	Men (29%)	Women (4%)
Pentecostals	Men (21%)	Women (2%)
Fundamental Protestants	Men (37%)	Women (1%)
Mainline Protestants	Men (33%)	Women (2%)
Liberal Protestants	Men (46%)	Women (8%)
Traditional Catholics	Men (21%)	Women (3%)
Moderate Catholics	Men (26%)	Women (6%)
Liberal Catholics	Men (35%)	Women (2%)
Other Catholics	Men (26%)	Women (18%)
Latter Day Saints / Mormons	Men (14%)	Women (3%)
Other Christians	Men (24%)	Women (9 %)

Church attendance and Pornography

The study was extended to those who attend Church service on Sundays – (i) those who attend weekly Church service regularly (ii) those who attend Church occasionally and (iii) those who never attend a Church service at all any time (Patterson and Prince, 2012). The percentage data on viewers of pornography in these three categories of people are summarized below.

- (i) Attend Church weekly Men (26%) Woman (6%)
- (ii) Attend occasionally Men (38%) Woman (9%)
- (iii) Never attend Church Men (53%) Woman (12%)

The data showed an inverse relationship. Those who attend weekly Church service on Sundays view less pornographic materials than those who never attend Church.

A Moral Decay

The Barna Research Group Ltd USA conducted, in October 2003, a telephone interview survey with a nationwide random sample of 1024 adults using its Barna Research Group telephone interviewing facility in Ventura, CA. The maximum margin of sampling error associated with the aggregate sample was ± 3 percentage points at the 95% confidence level. Adults in the 48 continental States were covered and it took

necessary precaution to ensure a fair distribution of respondents with respect to the geographic dispersion of the U.S. adult population. Multiple call-backs were used to increase the probability of including a reliable distribution of adults.

Secondly the respondents were both believers in God and non-believers. There were three arms in the survey: (i) Christians (ii) Other faith groups and (iii) Agnostics & atheists. The survey addressed seven moral issues listed below.

Barna Research Survey Results

Table 1: Percentage of Adults Who Consider A Behavior To Be "Morally Acceptable"

MORAL ISSUES	All Adults	Evangelicals	Born Again	Other Faith	Atheist/ Agnostic
1.	61%	27%	45%	69%	75%
2	60%	12%	49%	70%	87%
3	59%	15%	49%	71%	78%
4	45%	4%	33%	45%	71%
5	42%	7%	35%	47%	69%
6	38%	5%	28%	49%	70%
7	36%	7%	29%	46%	68%

Table Credit: Barna Research Group Ltd.

Seven cardinal moral behaviours chosen for survey

1. Gambling
2. Co-habitation without marriage
3. Enjoying sexual thoughts/fantasies about someone
4. Having an abortion
5. Having a sexual relationship with someone of the opposite sex to whom you are not married
6. Looking at pictures of nudity or explicit sexual behaviour
7. Using profanity

Faith can retard moral decay

The results of the above study have a significant bearing on the moral development in both groups of a population: (i) society as a whole and (ii) on the individual person as well. The following three conclusions can be drawn from the above critical data base: (i) all the three arms of the study are prone to wander into areas where angels afraid to step into (ii) even though Protestants and Catholic Christians were impacted they were not totally deprived of their morality and (iii) people with agnostic and atheistic worldviews are those who can very easily accept all the seven issues that were posed in the Barna research study as morally acceptable acts. The Evangelical Christians scored the lowest while the agnostics and the atheistic scored the highest in all the seven moral issues. It only shows that the faith or the worldview a person holds matters in these representations of moral development.

All round moral decay

The *Christian Post* (2003) also reported the results of Barna Research Group Ltd November 12, 2003 survey: "a majority of Americans believed that each of three activities were "morally acceptable." Those included gambling (61%), co-habitation (60%), and sexual fantasies (59%). Nearly half of the adult population felt that two other behaviours were morally acceptable: having an abortion (45%) and having a

sexual relationship with someone of the opposite sex other than their spouse (42%). About one-third of the population gave the stamp of approval to pornography (38%), profanity (36%), drunkenness (35%) and homosexual sex (30%). The activity that garnered the least support was using non-prescription drugs (17%)."

The Future of Morality

Brooks (2010) reported "*Study after study finds that Americans are not hierarchical. American children are raised to challenge their parents. American underlings are relatively free to challenge their bosses. In this country you're less likely to have to submit to authority.*

... Americans are now in a depressed state of mind. As China and India rise, nearly two thirds of Americans believe their nation is in decline". The fear of moral decline leads to a condition in which morality continues to decay" (Christian Post 2003, Patterson, et al 2012).

The Barna Research Group Ltd survey results were published in November 2003. Twelve years have elapsed and hence it is desirable to get a fresh look into the moral climate of the present and the emerging global society. If the emerging society has a majority of gay community then a new global bioethics may have to be developed for the new global gayism. The phrase "slippery slope" means that a course of action undertaken to correct one error leads to further dangerous disastrous unsolvable situations. In the long run, will the society trip into amoral abyss since further morality decay has been predicted?

Cardinal moral behaviour numbers 4 - 7 (Table 1)

Moral items 4, 5, & 6 are concerned with sexual morality. It is very interesting to note that only a very small percentage of evangelicals i.e. 4 to 7 % alone had considered that these four behaviours are morally acceptable and the majority of Evangelicals consider that these actions are definitely immoral. Why? It is because of their unmistakable belief that the entire Bible, including Genesis narrative account of creation (Genesis 1 – 11), is the revealed, inspired, infallible and inerrant Word of God. They generally "walk their talk". Their doctrinal teaching is contained in the following sexual morality statements: (i) No sex act before marriage (ii) Nothing outside marriage and (iii) No deviant sexual orientation other than the socially accepted tradition of male – female union in marriage. But some do give way to their basic instinct (4-7%) which only proves the rule.

Naked Truth is Tragic Truth

Does Genesis 1-11 prohibit pornography? There is no direct answer to this question since this word does not occur in Genesis 1-11. The word pornography does not occur because the practice was not in existence. But the naked truth is that this passage does record the action taken by Adam and Eve to cover their nakedness. There was an inner urge in them NOT to remain naked. If the word "nakedness" is the equivalent of the word "nudity" and since pornography mainly deals with the uncovering of a human body then Genesis 1-11 does indicate that it is

natural for a human being to remain body covered. Adam and Eve both switched fig leaves to cover their nude condition. But the creator God provided a better and durable instrument of skin to cover their nakedness. If pornography is morally unacceptable then to regulate the pornographic culture both human regulatory actions plus God's spiritual provisions are necessary. The tragic truth is that post-modern people's culture and technological culture have broken these two regulatory norms. The naked and the tragic truth is that pornography has come to stay.

Global Perspective - TFR

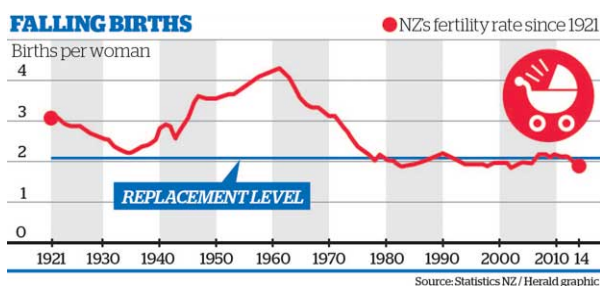
2012 Ranking	Country	TFR	2014 Ranking	TFR
1	Niger	7.52	1	6.89
2	Uganda	6.65	5	5.97
80	India	2.58	81	2.51
121	USA	2.06	123	2.01
137	UK	1.91	140	1.09
155	Netherlands	1.78	156	1.78
202	Japan	1.39	208	1.40
203	Greece	1.39	207	1.41
219	Taiwan	1.16	222	1.11
220	Hong Kong	1.09	221	1.17
221	Macau	0.92	223	0.93
222	Singapore	0.78	224	0.80

Note: source data for a few countries are taken from "The World FactBook" : Total Fertility Rate (TFR) CIA, USA.

Data were provided for a total of 222 countries in 2012 and for a total of 224 countries in 2014. In both the assessment years Singapore ranks the lowest TFR of 0.78 and 0.80 respectively. Some 50 years ago Singapore was a third world island nation. But now Singapore is one of the costliest cities of the world to live in. In 2015 its school educational system is Number One in global ranking. But with the lowest TFR Singapore is not doing well. In a few years time there will not be enough native born Singaporeans to run the country. In two years time the country could raise 0.02 of TFR (from 0.78 to 0.80). How long will it take to reach the required and desired level of 2.00 and above TFR?

Chief Damage - Fertility Loss - A Case Study

Rich data on TFR and spiritual health of New Zealand are available.



The above TFR graph can be dissected into the following four segments:

Phase 1 Segment 1	1921 to 1935 = fall
Phase 2 Segment 2	1935 to 1960 = rise
Phase 3 Segment 3	1960 to 1978 = deep fall
Phase 4 Segment 4	1978 to 2015 = point of no return

Chief Points to Consider

(i) Among the sexual revolutions the land-mark years are the following: the 4th revolution was started around 1920 and the 5th one was started around 1960. That there were two peaks with downward tripping points in the NZ TFR curve at 1920 and also at 1960 it is very tempting to come to a conclusion that these downward trips are due to the 4th and the 5th sex revolutions. But such a conclusion is not valid since it is not supported by ground truth. There is no documentary evidence to reach the above conclusion.

(ii) A chief point to consider is the fact that the 2nd deep fall which reached the replacement level around 1978-80 failed to recover even after 35 years. Again 1980s coincides with 6th sex revolution. It is a well known biological fact that same sex marriages are not child centring and can't produce biological parents – the father and the mother.

(iii) The chief factor(s) that enabled the fallen TFR curve to recover in the previous two cases – prior to 1920 and at 1935 – may be identified and that right recovery note may be struck again!

Stage I

Segments 1 & 2 constitute **Stage I**. It comprises of a fall and a subsequent rise. Troughton (2007) in his Ph.D thesis entitled "*Jesus in New Zealand 1900 - 1940*" outlines the socio and political and religious reasons which could be used to explain the fall and rise of TFR. His thesis revealed that in early days, NZ Christianity was influenced by the doctrines of both English and American evangelicals. But under the influence of Liberation Theology it tried to reinterpret Christianity in a social context (p 128) and hence social Christianity and moral campaigning were the focal points. There is no indication that the first sexual revolution of the Western world (1920) had any bearing on the declining TFR. There were three sex revolutions 1920, 1960 & 1980s. But the social factor that brought down TFR was alcoholism which broke the cohesiveness of Christian homes. In 1928 NZ voted on the issue of National Prohibition and secured only 294,453 (40.2%) votes which was less than the vote for National Continuance 374,502 or 51.1%).....(p 145). The upward trend of TFR did "lay in the combination of social activism and evangelical faith. Jesus was exemplary but also the source of regenerative life" due to the work of activist like Kagawa (p 176).

Stage II

Segments 3 & 4 constitute **Stage II** with a second deep fall and a subsequent flattening of the curve. There was no recovery. There was a deep spiritual slide. NZ became the 13th country to legalise same sex marriage by a parliamentary vote of 77 to 44 (April 17, 2013). Just 77 parliamentarians decided for the entire NZ and changed the definition of marriage. Strangely the 2nd point of decline coincides with the 2nd year of second sex revolution i.e 1960. The slide was deep and steady because the year 1970 was the golden year of pornography. There appears to be no

documentation on such relationship. Hence the blame was put on women's empowerment and her higher educational and earning capacity.

The New Zealand Herald published an article with a catchy title "*Money in the bank, fewer buns in oven: Why women are having fewer babies?*" "Babies are going out of fashion again as Kiwi women increasingly put work and study ahead of childbearing". Better education – with a five year Ph.D programme on hand women who are living in rich residential areas and with higher incomes are those who are likely to have lesser number of children (Collins, 2015). Fertility rates were now lowest where women were better educated, had higher incomes and were more likely to be in paid work. It may be added that the two sex revolutions may be the causal detrimental factor the low TFR. The death of TFR coupled with inner moral and spiritual decay will affect the security of a population under the heavy burden of detrimental socio cultural revolutions. Synergistic effect of a national declining TFR and a decaying morality is hard to rejuvenate spiritually for it takes a sustained production of high quality of human resource which is not there.

Suggested Remedy

"With Germany about to tip over the edge into population decline, and many countries already facing steep decline, there is little doubt that we need to support and encourage families with young children. Is encouraging more flexible work options for parents one way to do this? Even people who have more than enough money tend to work long hours, often also "catching up" on the weekend. It's pretty clear that long outside work hours and children don't go well together - the work of the home is important. Are people choosing long hours; or are the part-time and flexible options simply not there?" (Roberts, 2015)? All solutions end up with a question mark!

Incomplete Conclusions

There are more questions than answers. The conclusions will remain incomplete till remedial measures are found. The human marriage and parenting are being redefined. More and more fatherless homes and broken homes are being created. Will human society be stable? Our 'one home' mother earth is being over stressed to yield her natural resources to sustain the ever growing human population. Will the planet earth withstand the resource exploitation? Will the human species survive with the continued decline in human total fertility rate? With the onslaught of present and the future sex revolutions will the human society be led to the final destination – successful failure to close the "happiness gap".

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Japanese Bioethical Challenges Concerning Self-Management Support For Patients With Chronic Conditions: An Analysis of Quality of Life & Autonomy

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Abstract

Prevention and control of chronic conditions are global healthcare challenges. Patient self-management has been deemed essential for treating chronic conditions and improving the quality of patient life. However, the current Japanese system for supporting patient self-management of chronic conditions has received little ethical assessment. The first aim of this article is to provide an ethical analysis of current Japanese support for self-management of chronic conditions with reference to international discussions concerning self-management, developed mainly in western societies such as Europe, the United States. The second aim is to clarify the challenges faced by Japanese biomedical ethics concerning self-management support by focusing on the ethical concepts of quality of life and autonomy. This article identifies the following two challenges: [1] dispelling conceptual confusion concerning basic ethical concepts such as quality of life and autonomy, and [2] exploring the conceptual relationship between these ethical concepts, as they relate to providing support for chronically ill patients. By addressing these challenges and constructing a theoretical basis for radical change in support mechanisms, bioethics in Japan could contribute to efforts to construct a comprehensive support system for patients with chronic conditions, which organize variety kinds of supports, such as medical professional supports, supports from patient's groups, local community supports, familial supports, support in patients' workplace, and supports for patients' family members as well.

Keywords: Chronic conditions; Self-management; Autonomy; Empowerment; Quality of life; Japan

Introduction

The Japanese healthcare system has given the nation the world's longest life expectancy, with comparatively little expenditure (Hashimoto et al. 2011, pp. 1174-82, Japanese Ministry of Health, Labour and Welfare 2013, pp. 115-119, trans version p. 9, p. 32). Nevertheless, prevention and control of chronic conditions remain challenging with current Japanese

policies, as they do globally (Ikeda et al. 2011, pp. 1100-1103). Major chronic conditions, such as diabetes mellitus, hypertension, cancers, cardiovascular diseases, and cerebrovascular diseases, remain the leading causes of morbidity and mortality in Japan, consuming 30% of total national healthcare expenditure.

Since 2000, the Ministry of Health, Labour and Welfare has been engaged in the "National Health Promotion Movement in the 21st Century (Healthy Japan 21)," as a health promotion measure for citizens. This movement categorizes the four main chronic conditions—cancer, cardiovascular disease, diabetes, and chronic obstructive pulmonary disease (COPD)—as "lifestyle-related diseases."

The primary aim of this program is as follows: *"To promote people's health comprehensively through a decrease in premature death, the extension of the period during which people can live without suffering dementia or being bed-ridden (healthy life span), and so forth, in order to realize a society where all the nationals can live a healthy and happy life"* (Japanese Ministry of Health, Labour and Welfare 1999, part 2 chap. 6 sec. 4)

To this end, the second phase of the movement was launched in 2013, with five basic national goals including the prevention of the onset and progression of the four main chronic conditions. For example, in the case of diabetes, specific goals include "reducing the number of patients" and "increasing the number of visits for continuing treatment against diabetes."

If the Japanese government is seriously committed to these goals, the development of national programs for patient self-management must be achieved, because patient self-management is essential for successful treatment of chronic conditions and improvement of patient quality of life (QOL). As used herein, the term "patient self-management" refers to actions that patients take to manage chronic health conditions. Patient self-management extends beyond daily routines such as taking medicine, checking blood pressure or glucose levels, and monitoring symptoms. It also includes managing emotions, setting goals, working with health professionals, arranging schedules to accommodate treatment regimens, and developing social networks¹). Internationally, patient self-management has come to be regarded as essential for successful treatment of chronic conditions and improvement of patient QOL as individual well-being. There exist numerous efforts that seek to improve the quality of self-management support for patients with chronic conditions in the West, primarily in Europe and Australasia (Bodenheimer et al., 2002; Meetoo and Gopaul 2005; Aujoulat et al., 2007; Greenhalgh 2009).

In Healthy Japan 21, however, there are no programs aimed specifically at supporting patient self-management. In addition to this political negligence, Japan's bioethicists have paid insufficient attention to the social mechanisms that support self-management of chronic conditions, such as information giving, basic skills training, skill-building workshops, and counselling for problem solving. This article aims to provide an

ethical analysis of the current Japanese self-management support system for patients with chronic conditions and to clarify challenges in Japanese biomedical ethics concerning self-management support. Section 1 reviews the status of support mechanisms in Japan. Section 2 attempts to analyze this system. Section 3 identifies two bioethical challenges in Japan. Overall, this study argues that the theoretical basis of bioethics in Japan must be harnessed to create radical change in support mechanisms.

Current Japanese Support for Self-Management of Chronic Conditions

In Japan, patients who self-manage chronic conditions are supported almost exclusively in professional medical settings such as clinics, hospitals, or medical centers. There are, however, no standardized national mechanisms for supporting self-management. Support by medical professionals is generally provided along with treatment, and categorized as “patient education” or “instruction.” For example, many hospitals and clinics provide classes for diabetic patients. Specialists who assist patients with self-management are given designations such as “Certified Diabetes Educator” (Nihon To-nyobyō Gakkai 2012, pp. 3-6). Similarly, an accreditation system established in 2015 designates specialists who assist patients with high blood pressure as “educators” (Nihon Ko-ketsuatsu Gakkai 2015).

However, the previous two decades have brought significant changes in methodological concepts of patient education or instruction in Japan. The old style of education juxtaposed the role of professionals and patients. It regarded medical professionals as instructors who set goals for patients and informed them about their treatment regimens. Patients were expected to follow their instructions without questions or resistance. This perspective assumed that patients who did not follow their instructions lacked discipline or understanding of their conditions, and that they needed re-education (Yamaguchi 2008, pp. 2-3, Katsuyama and Akutagawa 2012, pp. 699-707). In contrast, the new style of patient education does not delineate professionals as providers of instruction and patients as its passive recipients. Rather, patients are regarded as active learners who make decisions, alter behaviors, and integrate self-management of chronic conditions into their lives. Medical professionals are partners who assist in setting and implementing goals, as well as, when necessary, identifying problems, reviewing plans, and redesigning them (Yamaguchi 2008, pp. 2-5, Ishii 2011, pp. 33-39, Nihon To-nyobyō Gakkai 2012, pp. 2-12).

This methodological change in Japan has been clearly influenced by ethical arguments regarding the concept of patient autonomy and such related concepts as “patient adherence,” “patient empowerment,” and “executorial autonomy,” which have been developed mainly in western societies (Funnell and Anderson 2004, pp. 123-4, Holm 2005, pp. 159-64, Williamson 2014, pp. 5-6, Naik et al.,

2009, p. 24). In short, autonomy is becoming more pervasive in the new style of patient education in Japan. For example, a guidebook from the Japan Diabetes Society refers to “patient empowerment” in the following manner: *“Collaborative relationships between patients and medical professionals are essential for the treatment of diabetes. In such relationships, medical professionals do not control patients, but patients control their own diabetic care. That is, “empowerment” means that patients are given both the ability to participate in their care as an active agent of diabetic care and to control their care and health-related behavior”* (Nihon To-nyobyō Gakkai 2012, pp. 9-10).

The ability to both participate in and control their care is indispensable for patients to acquire or recover control of their lives, i.e., to become or remain autonomous. Autonomy in the context of Japanese patients’ self-management entails self-control, responsibility, and independence. Many characteristics of patients with “lifestyle-related diseases” would certainly match the image of autonomous individuals. In Japan, symptom-free individuals with lifestyle-related diseases, such as diabetes, metabolic syndrome (visceral fat syndrome), or hypertension, who do not require medical support may subjectively be classified as “patients” at routine health checkups. This classification is a result of uniform diagnostic criteria for these diseases, which aim for early detection and prevention. Therefore, there are many patients in Japan who remain active in their lives and have high capacity to control their own lives. In this respect, the concept of autonomy has significant implications for ethical analysis of self-management support in Japan.

As shown above, in Japan self-management support for chronically ill patients has been exclusively provided within medical settings, and we can find the methodological changes in these medicalized supports. These changes have been influenced by ethical arguments over patient autonomy. Yet, when considering patient autonomy seriously, are the methodological changes in Japanese self-management support sufficient to empower patients or respect their autonomy? How can other ethical criteria (e.g., patient QOL) be considered in assessing the current Japanese support system for self-management? In the next section, in order to identify the challenges faced by Japanese biomedical ethics, we will analyze the current Japanese support system with consideration of two ethical criteria: autonomy and QOL.

Ethical Analysis of the Current Japanese Support System: Autonomy and Quality of Life

First, the concept of improved patient QOL is one of the basic ethical criteria for assessing self-management support systems. The improvement or preservation of patient QOL is usually regarded as a basic goal of support for chronic conditions in Japan, as well as in many countries, although without clear definition given to this concept. For example, improved

QOL is one of the established goals in Japan's national cancer control strategy (Japanese Ministry of Health, Labour and Welfare 2013, trans version chap. 2). According to a guidebook from the Japan Diabetes Society, "*preservation of quality of patients' life through successful control of blood glucose level, body weight, blood pressure, and serum lipid*" is one of the most basic goals of treatment for diabetes (Nihon Tonyobyō Gakkai, 2012, p. 24).

If our society or government is seriously committed to the goal of improved QOL, it is clear that the current medicalized support system is insufficient. This is because not only disease itself, but also the implementation of patient self-management and treatment, can adversely affect patient QOL. Self-management process affect all aspects of patient life, such as life style and work style. For example, patient self-management of chronic conditions requires patients to alter lifelong behavioral patterns and often to accommodate typical daily schedules, including household task and job. Self-management practices can limit patients' interactions with coworkers, friends, and family members by limiting the content of their meals, and sometimes affecting their identities or self-conceptions. Furthermore, self-management may require patients to reassess their pre-illness lives and reconstruct their life plans. The contribution of medical support to improved patient QOL is actually quite limited. For example, patients whose treatment involves radical changes in diet might be taught the importance of a proper diet, which foods are nourishing, and how to count calories. This type of instruction might not teach patients how to incorporate a dietary regimen into complex daily life, including family or job responsibilities. Instruction on such topics is indispensable for patients to implement self-management in their lives without diminishing their QOL.

If a society is committed to the goal of improving patient QOL, it is necessary to construct an appropriately comprehensive support system that encompasses the wide range of challenges that patients will face in implementing self-management on a daily basis. Proposals to construct comprehensive support systems are gaining support internationally. In 2002, for example, the World Health Organization (WHO) developed its Innovative Care for Chronic Conditions (ICCC) Framework, "a comprehensive framework for updating healthcare to meet the needs of chronic conditions" (WHO 2002, p. 1). The ICCC and its prototypical Chronic Care Model (CCM) are taking effect worldwide (Wagner et al. 2001, Nuño et al. 2012, pp. 55-64). In contrast, the primary contributors to improved patient QOL in Japan have been informal ones, such as family or local community, rather than healthcare professionals (Hiroi 2013, pp. 17-30). As the proportion of single-person households is growing (from 7.6% in 1990 to 13.1% in 2010; Statistics Bureau 2010, chap. 1, p. 7), the role of informal communities in this effort is now rapidly declining. Yet, our society has no substitutes for the traditional informal communities.

Second, from the point of autonomy, the methodological changes in Japanese self-management support can be welcomed for their emphasis on patient perspective. However, even the new style of patient education provides incomplete support for patient autonomy. In the new style of patient education, as in the old style, it is presupposed that patients are self-sufficient at implementing goals without assistance outside of that received in a healthcare setting. Within this system, if patients fail to visit a doctor regularly or to implement their own goals, regardless of the reason, patient attitudes tend to be regarded as something to be corrected within a medical setting. Many factors that affect successful self-management, however, are beyond the control of individual patients in the absence of assistance from other people. For example, it is often necessary for patients to rearrange their life or work schedules to incorporate dietary or exercise regimens. If patients are to adhere to dietary regimens or visit their doctors regularly, they require some help or cooperation not only from healthcare professionals but also from family members and colleagues. Patient self-management should not be considered an individual management issue. In order for patients to establish or regain control over their lives, it is necessary that their autonomy be taken into consideration both in clinical decision-making and in implementing self-management practices. Incorporating patient autonomy into self-management implementation involves some intervention or support from external sources, as well as from healthcare professionals.

Internationally, ideas regarding patient autonomy have been expressed through discussions of the concepts of "patient empowerment," or "executive autonomy" (Naue 2008, pp. 315-24, Lanoix 2013, p. 691, Williamson 2014, pp. 11-12, Van Geelen 2014, p. 22) 2). According to Lanoix, the concept of the patient as a person embedded in a support network of informal caregivers is essential for long-term illnesses. Efforts to construct systematic support for chronic patients to regain control of their lives have spread in Europe and the United States (Meetoo and Gopaul 2005, pp. 28-29, Aujoulat et al., 2007, pp. 13-20). For example, the United Kingdom (UK) nationwide Expert Patients Programme was launched in 2001. This program is based on "developing the confidence and motivation of the patient to use their own skills, information and professional services to take effective control over life with a chronic condition" (Department of Health 2001, p. 22). Similar programs are underway in Australasia, Europe, and the United States, although data regarding their effectiveness are poor (Greenhalgh 2009, p. 630).

In contrast, patient autonomy in Japan is still perceived as patient self-determination in clinical settings. In the context of Japanese discussions regarding support for chronic patient self-management, patients are usually portrayed as being self-sufficient agents who implement self-management goals without assistance. The term "lifestyle disease" can be taken to reflect such an impression of patients. The

implication of this term is that the diseases in question exclusively result from individual patients' lifestyles (which consist of their choices), commonly leading to the assumption that patients can choose to change their lifestyles, thereby completely preventing these diseases. If the discussion about support for chronically ill patients relies on these assumptions, the fact that patients require some support in implementing goals will remain neglected and the need to construct systematic support systems for chronically ill patients to establish or regain control over their lives will not be adequately recognized.

Bioethical Challenges in Japan

As discussed in the previous section, self-management support for chronically ill patients has thus far been exclusively provided within medical settings, and at the state level there remains little policy regarding self-management support of patients with chronic conditions as laid out in Healthy Japan 21. Though some efforts to improve quality of support through methodological change are observable at the medical level, even the improved versions of support are insufficient in providing for improved patient QOL, and incomplete regarding patient autonomy.

In order to properly address these defects in the current Japanese self-management support system, interdisciplinary efforts must be made to construct a framework for society-wide self-management support systems. Japanese bioethics could have an important contribution to make to this end. The remainder of this article addresses two challenges faced by bioethics in our country.

The first bioethical challenge is to explore the appropriate interpretation of, or dispel conceptual confusion about, two basic ethical concepts. Though the concept of QOL is prevailing in the context of healthcare for chronic conditions in Japan, interpretations of it are confusing. For example, according to a textbook for clinicians, "*QOL includes subjective concepts. Then we cannot assess quality of a patient's life objectively*" (Editorial committee of a manual for clinician 2008, p. 61). In contrast, guidelines for the management of hypertension say, "*since assessment of QOL of a patient with hypertension involves a wide range of assessment, such as assessment of comfortable feeling, physical symptoms, sexual functions, labor effectiveness, emotional states, cognitive functions, satisfaction for whole life, social activities, it is necessary to assess all of them objectively and comprehensively as far as possible*" (Committee for establishment of guidelines for treatment of high blood pressure in Nihon Koketsuatsu Gakkai, 2014, p. 36)."

In some instances, QOL is regarded as a subjective concept, while in others it is regarded as objective. As discussed previously by one of the authors of this article, we can reconcile these seemingly contradictory interpretations with a consistent conception of QOL by analyzing shared value systems in our country concerning "good human life." Under this conception, QOL can be interpreted in the following ways: 1) it can

be accurately evaluated through communication between patients and medical professionals (objective), but the relative importance of each factor involved in QOL depends on the individual patient's manner of thinking (subjective); 2) it is possible to establish general standards for QOL evaluation based on shared value judgments of what constitutes a good life (objective), but effective evaluation depends on each individual patient's condition (subjective). By providing a consistent conception of QOL, bioethics in Japan could clarify the limitations of medicalized support systems, and provide a theoretical basis for construction of a national level support system that addressed the wide range of challenges that patients will face in implementing self-management independently.

The concept of autonomy is required to explore an interpretation that is suitable within the Japanese social context. As noted in the previous section, new interpretations of autonomy, such as executive autonomy, have been developed in the context of patient self-management, while in Japan, autonomy is still perceived as patient self-determination in clinical settings. Although these new interpretations might gain support in Japanese culture, in which mutual assistance between families or local communities has been traditionally regarded as important, there remain some questions to be answered. Based on these new interpretations, some paternalistic interventions which frustrate patients' present autonomy might be suggested in the name of the preservation of future patient autonomy. Yet, are such interventions permissible? If they are permissible, how can we discriminate between permissible and impermissible paternalism? In order to explore support system configurations that purport to assist patients in establishing or regaining control over their lives, the appropriate interpretation of autonomy must be explored by clarifying these questions.

The second significant challenge for bioethics in Japan is to clarify the conceptual relationship between basic concepts. For example, the concepts of autonomy and QOL are perceived to be implicitly consistent with each other. Respecting a patient's autonomy is assumed to improve their QOL and vice versa. However, the relationship between these two concepts is not so simple. These concepts differ in nature, with the concept of QOL being categorized as consequentialist, and respect for autonomy as a non-consequentialist or deontological concept. Moreover, the demands of each concept may sometimes be conflicting. For example, it is easily imaginable that a patient knowingly prefers other activities to managing his disease, which is expected to degrade quality of his life in the long run. In this case, intervention on behalf of improved QOL might frustrate him as an autonomous decision-maker.

In Japan, as noted earlier, the uniform diagnostic criteria for some lifestyle-related diseases are designed for early detection and prevention of disease, hence, there could be many individuals who are classified as "patients" even in the absence of

symptoms during routine health checkups. Similarly, one of specific targets for primary prevention of diabetes in Healthy Japan 21 is “increasing the number of patients who continue their diabetes treatments.” Policies of this type for chronic conditions are usually justified in light of individual patients’ improved QOL, as well as social cost-benefit calculations. Under this rather paternalistic policy in Japan, some patients who are diagnosed at very early stages, and who lack any symptoms, might knowingly prefer other activities, such as working or studying, to managing their diseases. Moreover, there might be people who resist even being categorized as “patients” in the absence of any symptoms or health-related anxiety. In the case of such individuals, should their choice to reject any intervention for QOL be respected as autonomous choice? If not, for what reason? And what kind of support mechanism is ethically best for Japanese society?

By exploring the conceptual relationships or ethical priorities of QOL and autonomy, bioethics in Japan could help establish an ethically appropriate support system configuration.

Conclusion

Japanese ethical discussions about support for chronic patients are still at an early stage of development. It would be beneficial to begin these discussions by exploring the challenges faced by Japanese bioethics. This article identifies the following two challenges: [1] dispelling conceptual confusion concerning basic ethical concepts such as QOL and autonomy, and [2] exploring the conceptual relationship between these ethical concepts, as they relate to providing support for chronically ill patients. By addressing these challenges and constructing a theoretical basis for radical change in support mechanisms, bioethics in Japan could contribute to efforts to construct a comprehensive support system for patients with chronic conditions. Such a comprehensive system would integrate a variety of support mechanisms, including medical services for patients with chronic conditions, and support for other people who live with these patients.

Notes

1) Greenhalgh and other authors define “self-management” on the basis of biomedical views of one’s self. These narrower definitions restrict patient management of chronic conditions to such activities as taking prescribed medications. More comprehensive considerations, such as dealing with emotions and setting goals, would be categorized not as self-management but as “coping with illness.” The broader definition employed here is more common, notably in the UK’s Expert Patients Programme.

2) Other theoretical discussions of self-management and chronic conditions replace autonomy with other concepts. For example, Willems argues that agency rather than autonomy is needed to self-manage chronic diseases (Willems 2000, p. 24).

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Can the Principle of Procreative Beneficence Justify the Non-Medical Use of Preimplantation Genetic Diagnosis?

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Abstract

The Principle of Procreative Beneficence formulated by Julian Savulescu and Guy Kahane states that the parents have a moral obligation to select the best possible child, when selection is possible, by means of the genetic screening of the embryos. Savulescu not only advocates the genetic screening in order to avoid the disease markers but also advocates for selecting the non-disease genetic traits of an embryo which might contribute to the child's better future, e.g. the intelligence of the child or selecting a particular sex. In the paper, I put forward the question whether preimplantation genetic diagnosis is justified in the case of selecting the non-disease genetic markers. I explore the fundamental assumptions of the Principle of Procreative Beneficence as well as its moral foundation in order to understand Savulescu's claim. I argue against the pro-selection view of Julian Savulescu exploring the basic assumptions and moral foundation of the Principle of Procreative Beneficence. The Principle of Procreative Beneficence presumes that the non-medical and medical use of Preimplantation Genetic Diagnosis are mutually inclusive in the question of a moral obligation for the parents. However, I identify that this is not the case if we consider the possible consequences of Preimplantation Genetic Diagnosis to the potential life of the child; the non-medical and medical use of Preimplantation Genetic Diagnosis are mutually exclusive in terms of their implication on a child. The Principle of Procreative Beneficence also presumes a degree of parental obligation in the concept of 'significant moral reason' in the case of employing Preimplantation Genetic Diagnosis which is morally problematic. Finally, I argue that the moral foundation of the Principle of Procreative Beneficence is based on the 'common moral intuition' which is not an authentic source of moral truth; hence, the Principle of

Procreative Beneficence cannot justify the non-medical use of Preimplantation Genetic Diagnosis.

*When I was just a little girl
I asked my mother, "What will I be?
Will I be pretty; Will I be rich?"
Here's what she said to me
"Que sera, sera
Whatever will be, will be
The future's not ours to see
Que sera, sera
What will be, will be"*

[A popular song in the movie *The Man Who Knew Too Much* (1956)]

Introduction

A pronatal view of procreation seldom requires ethical justification. We take it for granted that we have an obligation to procreate. We presume an intrinsic blameworthiness for not procreating (Benatar, 2006; Overall, 2012). An extreme version of prenatalism not only advocates the obligation to procreate, but also extends the domain of obligation for parents to ensure the best possible life of the child. The Principle of Procreative Beneficence (PB) is one such extreme pronatal view in reproductive ethics. Julian Savulescu formulated the principle in his paper "Procreative Beneficence: Why we Should Select the Best Children". Further development of the principle was done in another paper titled "The Moral Obligation to Create Children with the Best Chance of the Best Life" in collaboration with Guy Kahane (Savulescu & Kahane, 2009). The principle states that the parents have a moral obligation to select the best possible child, when selection is possible, by means of the genetic screening of the embryos. Preimplantation Genetic Diagnosis (PGD) is a reproductive technology that makes it possible to discover the medical and non-medical genetic traits of embryos. By medical traits it means the possible risk of some genetic disorders or chromosomal abnormalities such as Down Syndrome and Cystic Fibrosis, whereas non-medical traits mean some non-disease traits such as intelligence, sex, or perfect pitch. PB justifies employing PGD not only for medical reasons, but also for non-medical reasons. It is less controversial to employ PGD in order to determine chromosomal abnormalities or other genetic diseases. Moral controversy arises when PGD is employed in order to select the preferred sex or certain genetic traits such as the intelligence of a child. The pro-selection view is divided on the issue of whether parents have a moral obligation to select the child with the best life or the child with a life worth living. Julian Savulescu claims that his formulation of PB is distinct from some other versions of PB (e.g. 'the prevention of harm' view or 'the obligation to ensure a minimally decent life for the child' view) and that it makes a stronger claim that parents have a moral obligation to select their child with the best chance of the best life. In fact, his proposed version of PB claims for a "significant moral reason" for the parents to ensure the best possible life of the child. The central inquiry of the

paper is to find out whether non-medical use of PGD can be justified by PB proposed by Julian Savulescu. To explore the issue, I put forward the question, can PB make such a strong claim that the parents have a moral obligation to select the best possible child by employing PGD? In other words, can non-medical use of PGD be justified, in terms of its claimed obligation, by PB? I argue against the pro-selection view of Julian Savulescu exploring the basic assumptions and moral justification of PB. PB presumes that the non-medical and medical use of PGD are mutually inclusive in the question of a moral obligation for the parents. However, I identify that this is not the case if we consider the possible consequences of PGD to the potential life of a child; the non-medical and medical use of PGD are mutually exclusive in terms of their implication on a child. PB also presumes a *degree* of parental obligation in the concept of 'significant moral reason' in the case of employing PGD which is morally problematic. Finally, I argue that the moral foundation of PB is based on the 'common moral intuition' which is not an authentic source of moral truth; hence, PB is not justified, with its morally problematic assumptions, to claim a moral obligation for the prospective parents regarding the non-medical use of PGD.

How Preimplantation Genetic Diagnosis Works

In Vitro Fertilization (IVF) is one of the Assisted Reproductive Technologies (ARTs) that has given the hope to the couples who have been unsuccessful to procreate for number of reasons. Generally, there is prenatal testing (the test for the fetus) available for couples who are at high risk of transmitting genetic diseases to their offspring. If the fetus is diagnosed with any sort of genetic abnormality, then the options are either termination of the pregnancy or giving birth to a child with a genetic disease. PGD is comparatively a new technology that detects the genetic conditions of embryos before implanting it into the uterus. A single cell from the embryo is taken by biopsy to detect the genetic abnormalities. Therefore, PGD has brought up alternative options for the couples who have known genetically transmittable disease. In IVF process, the goal of employing PGD is to diagnose for the specific genetic conditions for the embryos, not the fetus, before the pregnancy. Couples can choose an unaffected embryo after mutation analysis in the case of PGD which liberate them from the anxiety of a possible pregnancy termination and start a pregnancy with the knowledge of the genetic condition of their offspring (Fiorentino et al., 2006, p 670).

Currently, the technology is used mostly to detect the genetic abnormalities. However, in near future, there is a possibility to detect some non-diseases genetic traits of the embryos as well by this technology such as the intelligence or height of the child. One of the popular non-disease uses of PGD at present in the western countries is 'sex selection'. Couples may select the sex of their potential child from the available embryos. There are existing laws in different jurisdictions restricting the sex selection only to 'family balancing';

for example, a couple may opt for a baby girl if they already have two or more baby boys in the family.

The Foundation and Formulation of the Principle of Procreative Beneficence

The advancement of reproductive technology has made us rethink the parental moral obligation. Savulescu's attempt is to formulate a guidance principle for the prospective parents. He formulates the Principle of Procreative Beneficence and claims that the parents have a moral obligation to act in accordance with the principle. The principle says,

If couples (or single reproducers) have decided to have a child, and selection is possible, then they have a significant moral reason to select the child, of the possible children they could have, whose life can be expected, in light of the relevant available information, to go best or at least not worse than any of the others. (Savulescu & Kahane, 2009, p. 274).

Savulescu's principle conceives an underlying argument in it. Let us examine Savulescu's argument in the principle:

Premise 1: Parents have an obligation to care about the potential for wellbeing of their future children

Premise 2: Some specific genetic traits make our life 'most advantageous'

Premise 3: It is possible, by means of PGD, to select some specific genetic traits which can make the life of a child 'most advantageous'

Conclusion: Parents have a moral obligation to select those genetic traits in order to ensure the most advantageous life of their child.

The first premise of the argument discusses parental obligation to secure the wellbeing of their future children. Savulescu appeals to our common sense morality in order to justify parental obligation. Usually parents do care about the wellbeing of their children. We save money in order to provide the best care to our children; we select our partner with certain genetic attributes and desire our children to bear those attributes so that they can be benefited; we take time to prepare ourselves financially and materially so that we can provide the best environment to our children. According to Savulescu, common sense moral intuition says that it is morally wrong if parents do not concern themselves with their children's future life.

The second premise entails that some certain genetic traits of human beings contribute to making the life advantageous. For example, intelligence is such a trait by virtue of which someone can be successful in life. Or, a specific gender may serve as an advantageous condition for a child. The third premise says that it is possible now to select the genetic traits of embryos by means of PGD. Previously people had to depend on nature to have the desired genetic traits.

The conclusion infers that the parents have an obligation to select the best possible child so that he or she can lead the most advantageous life. If we look at the argument carefully, we see that the obligation inferred in the first premise has been extended to another degree in the conclusion. In the first premise, it talks about parental obligation in general. Whereas,

the conclusion extends the general obligation to a specific category i.e. obligation to select the best embryo. The meaning of general obligation implies that parents should be concerned about the future of their child. On the other hand, a specific category of obligation implies that if genetic selection creates a better future for their child, the parents should opt for it. What is the justification of this jump from the assumption of a general obligation to an obligation to a particular action? I shall discuss this problem later on.

Let us now analyze some of the significant properties of the principle. 'Significant moral reason', 'relevant available information', and 'best life' are the three important properties of the principle. Savulescu argues that with the relevant available information, the parents have a moral obligation to select the best embryo for the sake of the best possible life of their child. By 'relevant available information' Savulescu means the genetic information of embryos. There are both disease and non-disease genetic information available in the process of PGD. The PGD clinics are permitted to offer tests for about 250 genetic conditions or the genetic conditions licensed by the respective jurisdictions. Prospective parents can opt for any number of those tests of genetic conditions and have the genetic information of the embryos. However, the principle rests on some basic assumptions which, I argue, are problematic in nature.

Some Morally Problematic Assumptions of the Principle of Procreative Beneficence

Firstly, Savulescu presumes a *degree* of obligation in the formulation of PB. By 'significant moral reason', Savulescu means that the prospective parents have an obligation towards their potential child. However, he does not mean that the parents have an *absolute* moral obligation to ensure the best life of the child. Rather, he uses the phrase 'significant moral reason' to express a flexible concept of obligation. There are criticisms of such a flexible account of obligation in Savulescu's paper. Robert Sparrow writes,

Savulescu confuses reasons with obligations and moves between the claims that parents have some reason to want the best for their children and the more radical claim that they are morally obligated to attempt to produce the best child possible. (Sparrow, 2007).

Can there be a flexible concept of obligation? Savulescu argues that there is an obligation for procreative parents to ensure the best life for their child, but the obligation can be ignored in some exceptional cases. For example, there is no obligation to select the preferred embryo if the mother is exposed to any health risk due to the selection. Savulescu uses the term 'obligation' in the title of his paper; however, he replaces the term with 'significant moral reason' in his formulation of PB. This replacement, in my opinion, implies a *degree* of moral obligation. This is evident in his claim for a *non-absolute* moral obligation. But the question comes whether we can claim a degree of obligation. Can we have the concept of 'less obligation' or 'more obligation' in the realm of morality? Can we say that we have less obligation to select the best

embryo if the selection procedure involves a possibility of harm to the mother, otherwise we have more obligation? Clearly not, either we do have an obligation to do certain actions or we do not. There is no middle ground between them.

Secondly, Savulescu presumes the mutual inclusiveness of the medical and non-medical use of PGD in formulating PB. The problem of this assumption becomes clearer if we envisage the implication of the medical and non-medical use of PGD in the construction of the best possible life. In Savulescu's view, there are some genetic traits which can contribute to the formation of a healthy, successful, and happy life. If a couple avoids some genetic conditions such as Cystic Fibrosis or Down Syndrome, then it would help the child to have a better life in future without those diseases. Similarly, if a couple chooses some genetic conditions such as intelligence or height, then the child have a better chance to lead a better life than leading a life without those traits. Both cases contribute to the possibility of leading a good life according to Savulescu. But, do they have a similar implication? Are they mutually inclusive in terms of determining the parental obligation? Let us consider the current available diagnosis for the genetic conditions to determine genetic abnormalities and their implication to the construction of a good life. There is scientific evidence that some genetic traits cause some specific diseases. Currently it is approved in the UK to test for 250 genetic conditions (Human Fertilisation and Embryology Authority, n.d.). If parents want to avoid any specific genetic condition, then they can test it during PGD. However, there are scientific evidences to prove the correlation between the type of gene and possible diseases. This is empirically tested that the choices made by the parents in case of the selection of genes to avoid some certain diseases has a necessary relation to the chances of leading a better life. For example, there are identifiable genetic markers which cause immediate diseases like Down syndrome and Tay-Sachs. PGD can also identify certain genetic markers which might develop certain diseases like Alzheimer, Huntington disease, Hemophilia A and B, and Breast cancer in later life. That means, the avoidance of certain genetic traits contributes directly to the construction of a better life comparing a life with the diseases stated above.

Now, is it the same for the selection of non-disease genetic markers? More specifically, does the selection of certain sex, e.g. male, contribute to the construction of the best possible life of a child? In the disease case we have empirical and scientific evidence to the possibility of leading a better life for a child; whereas, there is no empirical evidence but a hypothetical assumption by a moral intuition to find the correlation between non-diseases genetic selection and the possibility of leading a good life. Therefore, the selection of non-disease genes is not equivalent to the avoidance of certain disease traits in the case of employing PGD. Savulescu argues for the same moral obligation for both *selecting* non-disease traits and

avoiding disease traits in order to have the best possible life of the child. Selection of non-disease traits and avoidance of disease traits are mutually inclusive in Savulescu's view which is morally problematic.

Now, how does this mutual exclusiveness of the choice of disease traits and non-disease traits make a difference to the parental obligation? I discuss the question whether parental choices of genetic selection have a necessary relation to the chances of the wellbeing of their children. It seems, when we read Savulescu, that selecting genetic traits of the embryos is directly connected to the wellbeing of the potential child. But, a critical examination reveals that the relation is not necessary, but is rather contingent. Genetic selection has very little to do to the formation of future life. We shape our life by everyday activities and thoughts. Our life is not the legacy of our genetic blueprint. Even complex symbolic information cannot be contained in the genes which are passed on from parents to offspring. Developmental psychology provides us proof of how we attain skills, a sense of identity, and the ability to form an empathetic relationship with others through environmental influences. The new research in the area of cognitive science and developmental psychology shows that genes are not the blueprint of complex mental imagery and processes, but rather they function as the initial catalysts of developmental process (Knox, 2004). Therefore, someone's success in life has nothing to do with his or her genetic inheritance. Even if we select 'smart genes' during PGD, that does not guarantee a successful life of the child. With an overarching view of genetic inheritance, PB ignores the human capacity of innovation.

Clearly, disease and non-disease selection of genes have different merits and different ethical considerations. Savulescu claims the same ethical considerations for both cases. Intelligence, certain sex, skin color, or height might work as a part of the constituents of the best life, but that does not mean that the best possible life is not possible without them. An intelligent person might end up miserable in his or her life. Recent studies in neuroscience and psychology have found a correlation between intelligence and anxiety. "Gifted children are prone to disharmonious development, which may result in the development of personality disorder, obsessional behavior, and anxiety disorder" (Coplan et al., 2011). Sometimes, the higher IQ might cause greater psychological fragility of a person.

In my opinion, it is morally obligatory to avoid passing on some specific genes if it may cause possible diseases; whereas it is not morally obligatory but morally permissible to select the non-disease traits of embryos so that the child has a possibility of leading a good life because of those genetic traits. Therefore, the selection of non-disease traits and avoidance of disease traits in PGD are mutually exclusive in terms of determining the obligation for the parents.

The Moral Foundation of the Principle of Procreative Beneficence

It is customary for the ethicists to formulate a moral principle and judge human actions on the basis of that principle. Usually the principles are justified by moral reasoning with a solid and reliable moral foundation. Savulescu's attempt is no exception. He formulates PB in order to judge the morality of certain procreative decision of the prospective parents. But, what is the moral justification of Savulescu's principle? He tries to avoid the complex philosophical justification of his principle, but rather he justifies his principle by the common moral intuition. He argues that people have general intuition about the concept of a good life. We also ought to do the best possible things for our children to ensure the best life. For example, we save money before bringing our child into this world. Or, for example, a sensible couple would wait some time if there is any health risk to procreate in a certain period. I completely agree with this common moral intuition. But can PB be justified by the common moral intuition? Hypothetically, we can easily think of counterexample of Savulescu's argument. For example, everybody wants the best life of their child but people would disagree about the means to achieve the 'best life'. One would not take bribe in order to ensure the best life of his/her child. The question comes, can we rely on such a principle which is based on just common moral intuition or should we look for a stronger principle in order to claim an obligation? Immanuel Kant in his *Groundwork of the Metaphysics of Morals* states some conditions of moral law should it claim an obligation. He says, *"Everyone must admit that a law, if it is to be valid morally, i.e., as the ground of an obligation, has to carry absolute necessity with it; that the command 'You ought not to lie' is valid not merely for human beings, as though other rational beings did not have to heed it; and likewise all the other genuinely moral laws; hence that the ground of obligation here is to be sought not in the nature of the human being or the circumstances of the world in which he is placed, but a priori solely in concepts of pure reason, and that every other precept grounded on principles of mere experience, and even a precept that is universal in a certain aspect, insofar as it is supported in the smallest part on empirical grounds, perhaps only as to its motive, can be called a practical rule, but never a moral law."* (Kant, 2002, p 24).

I do not claim that all moral principle should have such an ambitious plan, rather I claim that a principle must have a proper justification in order to claim an obligation. The counterexample proves that common moral intuition itself is not an authentic source of moral truth. Common moral intuition needs to have a higher rational justification. Moreover, in traditional logic an appeal to intuition is considered as an informal logical fallacy.

Common moral intuition in the case of disability: Julian Savulescu applies PB in the case of disability to show that PB can contribute in the debate of whether a parent can bring a deaf child in this world intentionally for the sake of the wellbeing of the child. However,

common moral intuition can also be misleading in the case of disability. Usually, non-disable people think that the quality of life of the people living with disability is extremely low. But, disable people themselves rate their quality of life higher than the assessment of the outside observers (Albrecht, 1999). This proves that a common moral intuition does not hold for the foundation of a moral principle.

Some Possible Objections

It might be said that Savulescu's principle claims a prima-facie obligation for prospective parents rather than a final obligation. A prima-facie obligation in this case means that the parents have an obligation to their child with some conditions. For example, PB does not claim an obligation for parents if employing PGD might cause any health risk to the mother. However, in my opinion, even if PB claims a prima-facie obligation for parents, we need to be cautious to frame it. Since, if someone does not fulfil an obligation, he or she is subject to a moral blameworthiness. Can we blame a couple if they do not select a non-diseases genetic trait of their child respecting the child's right to an open future? A further analysis will be needed in order to determine the conditions of the prima-facie obligation. For example, in the case of PGD, we need to determine the circumstances where parents have no moral obligation to select the non-disease genetic traits of their child. It seems that Savulescu is reluctant to generate a discussion of the general conditions of the prima-facie obligation for prospective parents. Rather, he emphasizes more on the parental obligation than the discussion of the circumstances where an obligation can be suspended. Therefore, claiming a prima-facie obligation will go in vein without a discussion of its conditions.

An objection can be raised that still we generally know that some genetic traits are good for people. Usually, intelligent people are successful in their life. But, there is no evidence that tells us that intelligent people always lead a good life. Perhaps, we mistakenly place all the credit to intelligence or some other genetic traits when we evaluate a successful life. Moreover, success has very little to do with a good life. Some people's genius and intelligence have contributed to the society in a great manner, but their lives were not good at all. A BBC documentary titled "Dangerous Knowledge" has explored how four brilliant mathematicians – George Cantor, Ludwig Boltzmann, Kurt Gödel, and Alan Turing – became insane for their genius and committed suicide after their breakthrough discovery (Malone, 2007). These counterexamples prove that it is at least questionable to take it for granted that some genetic traits are necessarily relevant to the concept of a good life.

Another objection might be raised in that if we are morally justified in employing PGD to identify the possible genetic diseases, then we are also justified to select specific genetic traits of the embryos. Proponents of this view often ignore the distinction between medical and non-medical use of PGD in terms of parental obligation which I discussed earlier.

Conclusion

Parental obligation to select non-disease traits of embryo is not justified if we critically investigate the constituents of a good life. The concept of 'good life' or 'most advantageous life' is too broad to be affected by a single event like selecting a non-disease genetic trait. We encounter billions of events in our whole life and a specific genetic trait has very little to do to influence the eventful life of a person. Someone might lead a good life because of his or her ability to manage emotion perfectly, someone might lead a good life without any contemplation and philosophical insight about the world around us. Think of the people who have the motto of 'eat, drink, and be merry'; aren't they leading a good life? Selecting a single genetic trait cannot change the whole course of life to make it good or bad. Rather, our everyday choices shape our life and create our future as well. Some people lead a good life simply by virtue of their luck, not intelligence.

In my opinion, selecting the embryos with certain genetic traits is not obligatory for the parents if we critically analyze the concept of moral obligation. There are at least two conditions of obligation, as we generally understand it. First of all, in order to hold a moral obligation, we must presume that there is freedom of choice, though there are huge debates as to whether freewill is a must to assume moral responsibility. We do not enter into the debate here, rather it is presumed, for the sake of the argument, that freedom of will is necessary for moral responsibility. In other words, we are responsible for such actions in which we have control over, or we have the ability to do otherwise. Secondly, our choices or actions must have a necessary relation to the chances. We do not hold any responsibility if our choices do not have a necessary relation to the chances. For example, Peter Singer argues in the context of the moral obligation of rich countries to help the poor countries. According to his view, the rich people cannot be blamed as murderer if they do not choose to help them. Because they are not actively involved to the death of those poor people (Singer, 2011). Surely, we do not hold responsibility for dying children in poor countries because of hunger or malnutrition. If I prefer buying a car to giving charity to Oxfam, I cannot be accused of murdering children in poor countries. Why don't I bear any obligation for death of the children in poor countries? Because, my choice of buying a car does not have a necessary relation to the chance of children's death in poor countries. Similarly, choosing a non-disease genetic trait does not have a necessary relation to the chance of children's future good life.

What kind of obligation do the parents have to their children, negative obligation or positive obligation, or both? Julian Savulescu, in his formulation of PB, presumes both negative and positive obligation of parents towards the children. The question can be formulated in terms of absolute duty and limited duty. Do parents have an absolute duty towards their children, or a limited duty? An absolute duty will concur them to ensure the best suitable condition for the

children, no matter what happens to the parents. A limited duty will keep some space for the parents to think of the means by which children's best life will be ensured. If we have the ability to prevent harm and if it does not cost much to us and if we do not prevent it, then it is immoral. This means, we only have a negative obligation towards others. Savulescu refuses the Prevention of Harm View on the ground of common moral intuition, although, he does not offer any additional justification for the positive obligation of parents toward their child. A possible objection in this regard is from a feminist perspective of ethics. For example, the ethics of care advocates a special kind of obligation towards the people we are related to. The parents have a special obligation to their children, and the children have a special obligation towards their parents. But, one thing should be noted that the ethics of care does not imply an unlimited obligation for parents. PB is too demanding for the prospective parents. It demands the parents to act out of altruism. Parental responsibility becomes a burden in the case of genetic selection of non-disease traits. Suppose, if something goes wrong in the genetic selection process, the parents will be responsible for all of the sufferings of their child because of their choice. Thus, PB ascribes a huge burden towards parents. PB does not clarify why parents should take such a responsibility. Ethics of care would not recommend parents to act altruistically as well.

Different ethical considerations are required for disease and non-disease genetic selection of PGD. Parents have moral obligation to protect their child from possible disease, and they should reject the embryos on the basis of available genetic information in the process of PGD. However, parents are not morally obligated to select the non-disease genetic traits. Non-disease traits are contingently related to the wellbeing of the child. The principle of Procreative Beneficence does not capture this contingent relation of selection and consequence. Hence, its claimed moral obligation for parents is flawed. Consequently, non-medical use of Preimplantation Genetic Diagnosis cannot be justified by the Principle of Procreative Beneficence.

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Deliberative Democracy for a Gene Editing Policy

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Introduction

How human beings know what is right and good, or even recognize an ethical problem is central to the ethics enterprise. Scientifically friendly logic and deductive reasoning follow a systematic course of reasoning, hypothetically from defining the problem to posing an answer. Such a process often fails to integrate deliberation, cultural values, and empirical knowledge into dialogical rationality. A case study is a mini-narrative in which a character represents others who may face a similar moral dilemma. A case study is not merely a laboratory of the mind – a think problem to be analyzed to find a solution. Science students may complain that bioethics is more conceptual than practical and are surprised to discover that deductive reasoning is not critical thinking. Knowledge is situated and contextual. Policy formation in the use of biotechnological innovations may represent a scientific solution to a problem, but policies affect many people in a variety of circumstances in particular and often profound ways. Deliberative democracy is central to the success or failure of informed debates about emerging possibilities rendered by scientific discovery. For example, within the past decade scientists discovered that bacteria can defend against viral infection by recording a segment of the viral DNA in the bacterial genome, creating a DNA memory bank.

These sequences were named “clustered regularly interspaced short palindromic repeats (CRISPR). Subsequently, the combination of an RNA directed endonuclease system CRISPR-Cas uses RNA to target a specific sequence and the Cas enzyme to degrade the DNA within the target zone which is then repaired. The potential was recognized as a way to edit DNA, to correct mutations and restore normal genetic sequences. Is the ordinary, average, reasonable citizen sufficiently informed to enter into meaningful dialogue about a policy governing gene editing? Deliberative democracy would advocate for an open, informed, debate in the process of establishing a policy for gene editing.

Direct-to-consumer testing

Research suggests that scientific literacy in general has a limited influence on perceptions. Generally, individuals within the U.S. have a positive perspective about science, claiming that science improves and prolongs life. Genetic testing and screening have been in place for decades with a physician’s referral. Beginning in 2002 when Myriad Genetics marketed a genetic test for GRAC to detect a type of early onset breast cancer, an evolution of print, television, internet advertising make direct to consumer genetic testing readily available without a doctor’s referral. Companies emerged including 23andMe, Navigenics, deCode Genetics and DNA Direct. A person can buy a paternity test kit for \$150 to determine if a child is his genetic progeny (Sandroff, 2010).

The Food and Drug Administration (FDA) expressed concern in 2010 that tests done by different companies may use different targets and report divergent interpretations. The Food and Drug Administration suspended genetic testing to review the status of the testing kits as to whether they are subject to FDA regulation. In 2011, NIH announced that a registry of genetic tests for more than 1,600 clinical conditions would be established. NIH could help by providing links between the medical community, consumers and genetic testing companies (Edwards and Huang, 2014). After review the results were made public: “FDA believes that in many circumstances it is not necessary for consumers to go through a licensed physician to have direct access to their personal genetic information” (FDA, 2015).

Genetic testing for some genetic diseases is straightforward and specific. Others fish for information among a dense number of possibilities for complex diseases where multiple pathways may be involved. The only requirement is the ability to pay. Anyone with a computer can search the internet for a genetic trait or disease. Whether the explanations are understandable is an open question. Whether individuals consult their personal physician about their concerns is unknown. It remains to be empirically confirmed if genetic testing leads to better patient outcomes.

Segue into Personalized Medicine

The emerging field of personalized medicine is a product of whole genome sequencing (WGS). It

claims to offer a best treatment option for any individual based on genotypic data taking into consideration such as how a drug will be metabolized, how long it lasts in the system, and how efficiently it is secreted. Tumors with particular types of mutations may reveal a specific therapeutic target such as an enzyme or surface receptor. To define and hone the field, NIH has launched a research project on personalized medicine that expects to enroll a million people, over a ten year period at the cost of one billion dollars (Yurkiewicz, 2010, Kaiser, 2015)

Whole Genome Sequencing is becoming more affordable (relatively speaking as it currently costs between one and five thousand US dollars). It is curious who will elect to have their own or a future child's genome entirely sequenced. What would be the benefit and what are the risks? Certainly WGS may reveal non-health as well as health related information. Susceptibility to a host of complex diseases can be tallied. Using filters, cardiac profiles can be culled from genes associated with cancer. Presymptomatic diagnosis of late onset diseases such as Alzheimer's and Huntington's raise questions about when a person might want to know, have the right or need to know? As more information accumulates, it should become more precise to separate the informative genetic tags from the rest of the data. WGS presents choices that appeal to autonomy-principled individuals, however, the wider social implications are often ignored until some insurance company or national healthcare provider makes it a condition of paying for genetic testing, screening, or in vitro fertilization (IVF) assisted reproduction (Dondorp, and deWert, 2013). Policy thus far has taken a cautionary approach but voices of strong advocacy are increasingly strong in the public square.

Assisted reproduction

More than five million babies have been born through assisted reproduction since the birth of Louise Brown. More recently mitochondria replacement therapy allows a donor's mitochondria to be placed in the mother's egg to eliminate metabolic diseases derivatives of mitochondrial genes. Since the genes in the mitochondria are not part of the chromosomes or nuclear DNA, the technique does not count as germ line therapy. While the child to be born from such manipulation does not consent to MRT, one might still think the future child argument germane to policy formation. John Harris points out that at the time of MRT no child exists (Harris, 2016). Consideration of the future interest of the child drives the debate from the individual autonomous choice to a larger social deliberation.

Evolution of gene therapy

Gene therapy has a mixed and disappointing history. Excitement over potential correction of a gene (adenosine deaminase ADA) to correct severe combined immunodeficiency disease (SCIDS, often called crib death) revealed that inserting a correct gene into the bone marrow of children would repair

and allow the immune system to regain function. This was exciting news. Five children in France received the treatment, but several years later; these children developed leukemia because the insertion site of the "correct" gene interfered with other normal genes (Check, 2002). Still scientists persist in trying to devise ways to intervene based on a sense of duty to help future generations live free of life limiting traits. As of 2013, clinical gene therapy protocols were being conducted in the U.S., Europe, China for cystic fibrosis, hemophilia B, Fanconi's anemia, Familial hypercholesterolemia, ADA deficiency and for three types of cancer but all of these studies are somatic cell therapies: none are germ line (Sanjukta, 2013). In some cases the genes delivered therapeutically are not stable, some of the vectors have proven toxic or allergenic, and insertion of the gene into a functional site of another gene can be harmful. Where earlier delivery systems failed, new hope has been ignited by the discovery of CRISPR (clustered regularly interspaced short palindromic repeats).

CRISPR Mediated Gene Editing

It began with a modest discovery that bacteria could fight off viruses based on keeping track of infecting DNA within the bacterial genome, a type of repetitive DNA memory bank. An RNA directed endonuclease system, CRISPR-Cas uses RNA to provide sequence specificity and the Cas protein to degrade the targeted nucleic acid which is repaired by a repair mechanism (Jinek et al., 2012, Mali et al., 2013, Hsu et al., 2014).

Jennifer Doudna of the University of California, Berkeley and Emmanuelle Charpentier now at Max Planck Institute for Infection Biology in Berlin, reported that CRISPR could cut specifically targeted sequences of DNA. Feng Zhang of the Broad Institute in Cambridge Massachusetts, examined more than 600 Cas9 enzymes from hundreds of bacteria in search of a smaller version that would fit into a small viral genome and found Cas9 in *Staphylococcus aureus* (Zhang, 2015).

In April 2015 a report was published by scientists at Sun-Yat-sen University in China on the use of CRISPR to edit a gene associated with beta-thalassemia in human embryos which were not intended for gestation (Liang et al., 2015). The article describes the team's effort to modify (edit) the human beta-globin gene in 86 embryos donated from IVF clinic. The results sound a note of caution. Of 71 surviving embryos, 54 had the edited changes in the right gene, however additional unintended mutations were found in other genes meaning that the specificity needs improvement. The data suggested that the technique has potential to remove mutations that cause genetic diseases and to replace the mistaken coding sequence with the correct functional one. While there were problems with efficiency and accuracy, the excitement this report generated was informative and the authors concluded that the system is not ready for clinical use.

Policy Evolution

The American Association for the Advancement of Science on its web site invites the public to vote on the most significant scientific discovery reported in a single year. The results were: Pluto got 35% of the vote, CRISPR 20%, Lymphatic system located in the central nervous system 15% and Ebola vaccine 10%. The reclassification of Pluto got more publicity perhaps than the discovery of CRISPR but the Ebola outbreak was heavily covered in the media. It is unclear if the significance scientifically as judged by persons who voted in the survey was based on understanding the science involved or on the recognition of an event heavily publicized. CRISPR is the latest in a series of “breakthrough discoveries” that raises hopes of editing human embryos in order to erase harmful mutations, improve the quality and quantity of human life and health. All technologies as they emerge need to be shown to be safe and effective in laboratory experiments (Harris, 2016).

Francis Collins, Director of the National Institutes of Health (NIH) released a statement on funding of research saying that none of the national research funds could be used to edit human embryos (April 29, 2015). The White House Office of Science and Technology Policy issued a Note on Genome Editing on May 26, 2015. The US House Committee on Science, Space, and Technology’s Subcommittee on Research and Technology held its first congressional hearing on genetically engineered human DNA in June 2015. The International Bioethics Committee of UNESCO updated their report on the Human Genome recommending a ‘moratorium on genome editing of the human germline’ in Oct 2015. This flurry of responses indicates several things. First there was already in place a prohibition from UNESCO and the Council of Europe and the European Union which viewed germline modification as unethical and an abuse of human rights. The US federal research budget prohibited research involving creation or destruction of human embryos as well as germ line modifications. The US FY2016 budget withheld funding for human embryo editing research (Reardon, 2015).

Relatively small percentages of the population seek reproductive assistance. Given the limited use, even if the ability to genetically test, select, alter the embryos were approved, it is unlikely that the human gene pool would be radically altered. There is a risk that a subpopulation of people would become genetically rich (Powell, 2015). Genetic injustice challenges us to achieve greater justice. Policies ought to represent the rational, dialogical, common good of the community (Smith, 2013)

Framing the Debate

There is no such thing as an unframed message. Framing refers to the idea that how information is presented has an impact on how the public receives the message. The importance of framing for science communication has been documented (Scheufele, 2013; Nisbet, et al., 2003). Framing of a scientific discovery or communication intends to make the

message understandable. The challenge is to frame the message so that the most dialogic communication follows to shape public policy. Research shows that there is a lifecycle of frames in public discourse, “starting with initial excitement about the promise of social progress and the economic potential of new technologies, then shifting to concerns about scientific uncertainties, risks and moral concerns, into framing the technology in terms of the societal controversies surrounding it” (Scheufele, 2014 p 13589).

Public attitudes toward issues such as climate change are not uniformly based on a comprehensive understanding of the science involved. Research has shown that public opinion often relies on the easiest retrievable context to form a judgment. When genetically modified food was called “ Frankenfood” it had a negative impact. When “climate change” was called “global warming” people experiencing a severe winter storm, laughed. What influence does CRISPR being a “breakthrough of the year” have on the debate? Knowledge does not always translate into positive attitudes about a scientific discovery. It is hoped that complex scientific information can be translated in ways average citizens can understand inviting a deliberate process to shaping policy.

Is “editing” the most neutral term? Metaphors operate consciously and subconsciously in complex ways. Does it have a metaphorical influence on the discussion of germ line therapy? Policy formation should reflect a deliberative dialogue with knowledge about the technology, how it works, how it could be used, what is unknown, about potential negative as well as positive consequences, and the broader impact such technology could have on the whole human family.

Meaghan O’Keefe et al. (2015) examined articles in the public media mentioning CRISPR and found that the most common metaphor for the genome was “text” and the idea of “editing the text” was used to emphasize what can be done to “correct genes.” In these analogous and metaphorical explanations there was no mention of risk. “We need metaphors for CRISPR that indicate the technology’s uncertainties and unknowns, and that convey its current value to basic research and potential clinical and public health benefits....Metaphors should accurately represent how the technology actually works and can be used, should avoid reductionist effects, and should allow for understanding of bioethical implications” (O’Keefe, et al., 2015).

Student survey

Interested to know what various level students know about CRISPR and what they think the ethical public policy should be, I engaged students in four classes in a survey. The classes included a freshman honors class (AIDS and Ethics, Honors 102), an upper division undergraduate honors/philosophy course (Global Issues in Public Health, HN/PHIL 316), Biology Senior Seminar (Bio 470) and a first year graduate course in Molecular Genetics (BMS 524). The questions and resulting responses are presented in Table 1.

Table 1 Survey on Gene Editing

	BMS 524*	Bio 470 *	HNPL316*	H102*
Age:	22-45 (29)	21-26 (23)	17-33 (26)	18-19 (18.5)
Gender:	50% female	90% female	66% female	73% female
Religious preference:	Christian 45%	20%	50%	47%
	Muslim 18%			
	Jewish			14%
	None 36%	80%	36%	53%
Political affiliation:				
	Democrats 30%	50%	54%	38%
	Republican 10%		7%	15%
	Independent 20%	10%	23%	15%
	None 40%	40%	15%	31%

1. Which of the following requires retrieval of sperm and eggs to achieve fertilization?

a) In vitro fertilization	82	80	85	62
b) Cloning			7	
c) Sexual intercourse	18	10	7	37
d) None of the above		10		

2. Louise Brown was first human birth using

a) IVF	72	90	100	87
b) sexual reproduction				
c) cloning	18	10		12
d) none of the above	9			

3. Preimplantation genetic diagnosis involves embryo

a) selection	27		7	32
b) DNA analysis	63	20	20	30
c) IVF				23
d) all the above	9	80	70	30

4. A sheep named Dolly was the cloned animal that brought ethical debate about the possibility of human cloning.

a) True	100	100	100	100
b) False				

5. Objections to human cloning include

a) right to genetic identity				
b) synthetic and unnatural	18			12
c) unanticipated harm				
d) all of the above	82	100	100	87

6. Natural reproduction produces identical twins 3 out of every 1000 births

a) True	34	80	85	80
b) False	63	20	15	12

7. MRT is a process of replacing genetic mother's mitochondria with mitochondria from another female donor.

a) True	81	80	76	86
b) False	18	20	23	13

8. Mitochondrial genes have no influence on identity conferring features

a) True	45	50	31	20
b) False	54	50	69	80

9. The UK but not the US has a regulatory oversight group for human reproductive issues

a) True	60	60	69	60
b) False	40	40	31	40

10. Harms occur through natural procreation with normal genetic lottery

a) True	72	90	91	96
b) False	27	10	8	12

11. Post conception actions by a mother can cause serious defects

a) True	90	100	92	100
b) False	10		8	

12. Consent is a process of informed choice

a) True	90	100	100	100
b) False	10			

13. Deciding to use MRT should be considered based on the child's

a) right to consent	18	20	14	14
b) open future				
c) best interest	72	80	86	86
d) none of the above	10			

14. CRISPR editing of embryos is opposed as

a) unsafe	36	10		
b) playing God	10	7	6	18
c) unnatural	10	80		6
d) all of the above	54		92	87

	BMS 524*	Bio 470 *	HNPL316*	H102*
15. Embryo editing is intended to correct mutations so that a child born will not have a genetic disease				
a) True	81	100	92	94
b) False	18		7	6
16. Gene editing is still in research phase				
a) True	90	90	69	88
b) False	10	10	30	12
17. Gene editing research is banned for all research funded by FY2016 US budget				
a) True	36	40	46	66
b) False	64	60	53	33
18. If you were aware of a genetic risk of a disease that limits human life and causes suffering would you:				
a) use IVF to select an embryo without the genetic risk	50	33	25	23
b) use gene editing if available	8	16	31	23
c) accept whatever child produced by natural procreation	16	11	6	17
d) adopt a child	23	38	37	35
19. Have you read about and formed opinions about gene editing?				
a) Yes	63	60	42	18
b) No	36	40	58	81
20. Do you support research and human use of gene editing in human embryos?				
a) Yes	72	70	53	68
b) No	18		15	25
c) don't know	9	30	30	6

- BMS 524 is a graduate course in molecular genetics within the Biomedical Science M.S. program
- Bio470 is the senior seminar for biology majors
- HNPL316 is an honors course for undergraduates: global issues in public health
- H102 is a freshman honors seminar, AIDS and Ethics.

Interestingly 80% of students know what is involved in using in vitro fertilization, that Dolly was the first cloned animal, and that harms do occur through natural procreation. Only 50% understand that mitochondrial genes do not confer features on the future child in the same manner as the nuclear genome, and 80% think MRT should be considered in the “best interest of the future child.” Most, 80%, recognize object to human cloning on the basis of the right to genetic identity, using synthetic and unnatural means, and/or unanticipated harm.

Regarding CRISPR and the promise of gene editing, the results were more varied. Asked why some would oppose gene editing, 10-36% said it was unsafe, 6-18% said it is “playing God”. That gene editing was perceived to be unnatural varied widely from 6 to 80%.. The majority (80-100%) think gene editing intends to correct mutations to relieve the burden of genetic disease but 69-90% recognize that the technique is still in the research phase and not ready for clinical practice. Fewer (36-66%) knew that genetic editing in human embryos was excluded from the U.S. FY2016 budget. Personal opinion varied about what they would do personally if faced with risk of passing a genetic disease to a child. Most interesting was the response to whether they had read about gene editing which increased with educational attainment as one might expect. The majority of students admitted they supported research on gene editing in human embryos. The suggestion is that whether they understand the details and science behind gene editing, they think research should continue because it MIGHT prove useful. This is where the scientific potential should influence political policy formation. This is a very limited sample and is a snapshot of

people with an interest in science, so no conclusions should be drawn about how they represent the population at large.

Conclusions

UNESCO Universal Declaration on the Human Genome and Human Rights stressed the duties of mutual assistance among nations, to the “common welfare of humankind” (UNESCO, 1998). The shared content of the human genome points to a unity among human beings and is factually and symbolically the heritage of humanity. If the market economy harnesses the applications of genetic information for commercial gain, the common heritage of humankind risks becoming a divisive factor instead of a tool to promote wellbeing (Cahill, 2001). The daily news raises questions related to emerging technology, the cost of health care, whether the research agenda actually promotes better quality of life. Technology evolves, equipment is expensive, professionals doing research are highly skilled and what is discovered today may not become part of a standard medical practice for generations (Boyd, pp121-128). Public policy generated from deliberative democracy is difficult in a polarized political climate. Daniel Callahan observed the difficulty in 2005 and it is even more intense today: “If you are a conservative and speak freely, the liberals will go after you – and not simply to refute your ideas, but to signal to the world that you are a moral threat to medical progress, unprejudiced reason, and the great struggle for human freedom. If you are a liberal, and speak freely, the conservatives will go after you, sometimes implying but usually saying outright that you are a menace to the sanctity of life, human dignity, and the deepest of Western values.

. . . If bioethics is to retain its vitality and be taken seriously, it will have to find a way to extricate itself from the culture wars" (Callahan, 2005). Healthy dialectic invites difference, helps us examine issues, and concepts in ways that value the tension as a means of advancing knowledge and understanding. Technology by design and intent is for the use of people. It is the choices people make in how to use technology that bears the greater moral accountability (Boyd, J. and Boyd, A., 2014). The balance of good (helpful) vs evil (harmful) will influence individual choice to use or not use this technology, but only if the technology is available to choose. Certainly there is little to no pressure to make gene editing mandatory, but to allow available when proven safe and effective through more research.

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Guiding Bioethical Principles through Issues of Colonisation

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Abstract

Current bioethical principles fall short on addressing the ethical and/or moral permissibility of bioethical practices such as biomedical procedures, clinical research, social science research and other practices of the same nature. Bioethical principles of autonomy, justice, informed consent, beneficence and non-maleficence and others are pseudo-justification of ethical codes that allow ethical permissibility of such practices through the limit-situation imposed by agents of power and knowledge. The vertical nature of power and knowledge predisposes other agents such as low socioeconomic status (SES) patients/subjects to other forms of ethically and morally impermissible practices that these current guideline fail to acknowledge and answer. The issue of colonisation, with implication on this power and knowledge hierarchy, gives light to the oppressive nature of the different bioethical practices. The understanding and acknowledgment of the existence of the oppressive nature of these practices may lead to more genuine relationship between the wielder of power and knowledge (doctor-researcher) and of the vulnerable agent (low SES patient/subject). This research shows the importance of the application of other philosophical theories such as postcolonial theory and critical theory in the development of a more socially aware agent, and how the current principles anchored on Western philosophies adhere to reactive formulation and implementation of these principles.

Keywords: Ethical Principles, Colonisation, Oppression, Critical Theory, Postcolonial Theory

Introduction

The current ethical guidelines that pervades biomedical practice, clinical research, social science research, and other such practices are at most reactive to cases of exploitation and unethical research conduct (Emanuel, Wendler & Grady 2000). It is a reaction to infamous cases such as the Nazi and Japanese medical experiments, which resulted in the primacy of autonomy and informed consent in the conduct of clinical research and other unethical practices which resulted in the formulation of the current ethical guidelines. Common to these cases are individual's agency as participants rather than subjects to the practices. Moreover, the general acceptance of the existence of these unethical practices lends itself to ethical scrutiny, and as such subjecting it to ethical review and under ethical guidelines. However, these bioethical principles tend to fail when they follow pseudo-justifications of what makes a practice ethical

or moral between agents of power through false relationship because of hierarchical nature of power and knowledge (Foucault 1972-1977).

Nevertheless, the reactionary shortcomings of the formulation of ethical guidelines on these infamous cases opened the discussion on the existence of different vulnerable groups that are dominated or subjugated in terms of the hierarchical nature of the power structure of the medical process, agents and institutions. This paper focuses on low socioeconomic status (SES) charity patients as a vulnerable group in medical research and clinical trials, where their enrolment in charity care predisposes them to possible oppressive nature of the practice. Furthermore, their agency as an oppressed group is no less different in the agency qualified to Indigenous People, as such, oppression as a result of a colonizing system should be further examined as a guiding ethical principle in the conduct of biomedical practice, clinical research, social science research and other such practices.

Colonisation will be forwarded in the current discussion of the current ethical guidelines used in clinical research, as its exclusion serves as a gap in the ethical conduct of biomedical and clinical research practices. The application of biocolonisation in the conduct of bioethical research involving Indigenous People (IP) should serve as a guide in the inclusion of colonisation, as an ethical value, in the conduct of research involving vulnerable groups. This paper shows that other vulnerable groups such as low SES charity care patients/subjects are not fundamentally different from other forms of colonisation that IPs experience especially in the context of bioethical research. As an overarching theme, low SES groups are prone to some form of colonisation in the conduct of research, which the other ethical values cannot respond to, as colonisation is beyond their ethical or moral scope. Lastly, the paper does not aim to discredit the other ethical values currently used in the ethical guidelines but to highlight the need to include colonisation in the guidelines in order to fully realize the conduct of ethical research.

The Health Care System, Vulnerability and Colonisation

The current climate of health care system and how the implication of its implementation around the world inherently carries with it the issue of vertical power relation, where, the institution together with the health workers carry with them a hierarchical nature of power over their patients (Foucault, 1972-1977). The current ethical guidelines on ethical medical practice, clinical research and other practices of the same nature fails to address this, thus, they fall short in the ethical conduct of these practices if this is not acknowledge and put into practice.

Different countries practice health systems compliant with the Declaration to the Right to the highest standard of health (WHO 2013a). The healthcare system a country implements is a product of its "unique conditions, history, politics and national character, which are in constant reform" (Tanner 2008:

6). This does not necessarily mean universal access across social classes as the rate in which those who belong in the poorest income quartile seek services drops by eight percent in private hospitals and a drop of 26% in public hospital if hospital bill increase by a percent (Tan 2001). This shows that the poor are at a disadvantage in accessing healthcare, a climate of vulnerability to those who seek charity care such as those belonging to low SES. Socioeconomic status variables (income, education, race, etc.) could serve as indicators of health outcomes, and with increasing socioeconomic disparity (UN 2013) and health care cost (Drechsler & Jutting 2005), there is an inevitability for individuals in low SES groups to access health care through free or subsidised care such as charity care. SES have been shown to have implication on the measurement, access and administration of health care quality and outcomes (Asch, Kerr, Kessey, Adams, Setodji, Malik, & McGlynn 2006; Fiscella 2004) such as in caring for patients under low SES group by physicians and other health care workers (Bernheim, Ross, Krumboltz, & Bradley 2008). Personal and financial strains have negative effects on the attitudes of physician concerning low SES patients such as in the acknowledgment and exercise of autonomy and other ethical guidelines in the conduct of medical procedures.

Given the above examples, vulnerable and marginalized groups carry the highest burden when it comes to issues related to the attainment of standard health care. Those who are at a financial disadvantage due to the financial burden of a health care insurance submit themselves to other forms and ways of acquiring health care through uncompensated care. Low SES groups usually disproportionately represent those who access charity care, as these groups belong to the low-income uninsured population (DeLia 2007). This has led to cases where these groups are subjected to different clinical research practices, which can be a side effect of their enrolment in charity care. A US survey shows that teaching hospitals and medical school faculty practice groups are the major health care providers of charity care (AAMC 2013). Together with providing charity care to the uninsured, these institutions maintain their core mission of medical education, biomedical research and innovative patient care. For instance, various medical schools integrate clinical research in their curriculum (Laskowitz, Drucker, Parsonnet, Cross, & Gesundheit. 2010), which provides a high percentage (40%) of charity care in 2007 (AAMC 2013). Patient/subject's socioeconomic status expose them to be dominated or subjugated under authorities such as doctors, researchers and medical students who have research interest in them as an available controlled or manipulated research group, and sometimes are forced to show deference to show gratitude through unwilling participation to clinical research procedure as an implication of the health care they received through charity care. These considerations should inform ethical guiding principles in dealing with patient/subject in low SES group as they exhibit multiple vulnerabilities

as shown by Kipnis' taxonomy of biomedical vulnerability (Kipnis 2001).

"The sensitive understanding of vulnerability—the many precariousnesses that afflict the human condition—exposes a certain universality in these themes even while grounding a broader case for kindness and sensitivity. None of us is without some cognitive limitation. Everyone is subject to juridic authority, not all of which is wisely benevolent. Socialization itself entails patterns of deference. All of us face an eventual and too real prospect of medical exigency. And no one is immune from extreme need and the harms that can flow from deficits in the systems we count on to provide us with essential services and protections. Nor are researchers the only ones who need to learn how to engage the vulnerable with sensitivity and honor. The topic surely has an importance extending beyond the boundaries of research ethics" (Kipnis 2001: 10).

The arguments above substantiate how individuals in low SES are vulnerable agents in bioemmedical practices, specifically in health care and other forms of research. Freire (2006) further argues that current ethical guidelines are a function of a neoliberal system, in which he explains,

"We need to say no to the neoliberal fatalism that we are witnessing at the end of this century, informed by the ethics of the market, an ethics in which a minority makes most profits against the lives of the majority. In other words, those who cannot compete, die. This is a perverse ethics that, in fact, lacks ethics" (Freire, 2006: 25-26).

Socioeconomic status, together with age, political, ethnic background or gender, should not prevent an individual or a group from the right to health, a fundamental component of human rights and a life of dignity (WHO 2013a). But with a neoliberal slant, where autonomy, benevolence, non-maleficence, informed consent and justice are mechanisms to provide legitimacy to current practices, it fails to become a guideline on genuine ethical practice. These ethical principles are **reactionary at best and limited in addressing current hierarchical power imbalance between patient and medical practitioner at its worst**. Power imbalance, or the hierarchical nature of power should be addressed especially as it exists between a patient and healthcare practitioner or researcher. In colonisation, domination is a central theme that has implication in the control by individuals or groups of other individual's or group's territory or behavior (Horvath 1972). Colonisation is not ahistorical, as domination exists across time in the subjugation, oppression and exploitation by an agent over another agent. Colonisation could be equated to exploitation in terms of economic variables (Marxist-Leninist conception of colonialism) or as a culture-change process (anthropology) (Horvath 1972). Colonisation consists of repeated and more or less successful attempts of the core (coloniser) to create a periphery (colonised) and impose political control in order to exploit the colonised economically (Sanderson 2005). Through

the process of generalization, there exists a case of oversimplification of colonialism in which J. E. Spencer commented, "this becomes quite clearly a case of the West trying to impose a simple universal definition of morality in aggression upon all the practitioners thereof" (Spencer in Horvath 1972: 54). Beyond the resource and territorial conquest concept of colonisation, other colonial theorists defined colonisation in terms of oppression, the oppressed as subhuman agents, otherness, colonizing gaze, power imbalance, the primitive vs the scientific or the modern and labor theory to name a few (Freire 2006; Nandy 1983; Fanon 1986; Hooks 1992).

Freire (2006) 'consistently argued that a thorough understanding of oppression (in light of colonisation) must always take a detour through some form of class analysis' (p. 13). This class analysis will allow us to further understand the ethical permissibility of clinical research not only through the hegemonic universal definition of morality by the West but also through the lens of the oppressed. This is evident in the class stratification, which exists between the clinical researcher and the research subject, where hierarchy of knowledge, power and wealth exists.

Colonisation as a bioethical principle (biocolonialism) is specifically applied on the temporally extended power imbalance between Western and "indigenous" cultures and contemporary practices of cultural imperialism (Whitt 2009). Within the context of biocolonialism is the commodification of knowledge and of genetic resources, which is at odds with the respect, and other ethical values, which indigenous communities rightfully have (Whitt 2009). The OCAP principles or "Ownership, Control, Access and Possession" is embedded in the ethical guidelines of values applied on research involving indigenous people (Burgess & Tansey 2009). Colonisation in Indigenous People such as the First Nations of Canada are characterized by "colonially-created cultural disruptions that compound the effects of dispossession to create near total psychological, physical and financial dependency on the state" (Alfred 2009: 42). Colonisation is a result of cumulative and ongoing effects of dependency which results in social suffering, unresolved psychophysical harms of historical trauma and cultural dislocation, which limit their individual and collective autonomy (Alfred 2009). The specificity of the values being applied to research involving indigenous people, considered as a historically colonised and oppressed group, should support the application of these same principles on other colonised or oppressed groups.

As shown in the previous sections, low SES groups are prone to physical, psychological and financial dependence in the access of health care; this dependency is akin to the dependency that IPs experience. The context of dependency should not be mistaken as the dependency seen between a child and a parent, the mentally-handicapped and their caregivers, and other such types of dependency. This dependency is rooted in the ongoing process of colonisation, which SES groups experience as a result

of unresolved historical, political, economic and sociocultural domination. Accordingly, as psychological, physical and financial dependency of IPs is considered as the determining factor in the inclusion of colonisation as an ethical value in research, as low SES groups exhibit these same characteristics, colonisation should then be considered as an ethical value in the conduct of biomedical and clinical research practices involving low SES groups. The acceptance and recognition of the ethical implication of colonisation should not only apply to a specific group such as IPs, rather, to groups who are historically oppressed or colonised. In which individuals of low SES belong to. Their history of oppression results in their low SES and creates a continuing reality of domination and oppression.

The ethical guidelines as limit-situations

Ethical research guidelines are a function of the medical or experimental controversies of the time in which they were formulated in order to prevent future scandals to occur or ever happening (Emanuel and others 2000). Ethical justifications of these ethical guidelines are based on historical and ethical reasons, which supported the different ethical values. The crux of this strategy is that it allows further scrutiny of a certain ethical issue at hand but neglects to account for other underlying or related ethical issues. The given ethical requirements are subject to this problem, in which ethical requirements in the conduct of clinical research such as informed consent and favorable risk-benefit ratio is a product of a code of ethics such as the Nuremberg Code (Emanuel and others 2000). Code of Ethics are prone to pseudo-justifications, as moral values such as maximizing happiness do not inform us what to do or what action or type of action to be taken (Muresan 2015). Relevant ethical issues might have been taken into account but the ethical value of non-exploitation is not enough to draw upon the context of colonisation, which exists in developing countries.

A further review of the current ethical guidelines shows that they were developed in response to medical/research problems or scandals. They are incomplete and only respond to the current concerns and therefore lack a systematic ethical framework. Patients/subjects in low SES as a subpopulation, have a unique characteristic, which makes them vulnerable to certain clinical research beyond these ethical guidelines. The ethical context of colonisation, which is applied on the conduct of research (social, clinical or scientific) on Indigenous people; consideration for further protection of low SES charity care patient/subject should be explored.

The history of colonisation, which brought about injustices and oppression, seen in IPs is mirrored by the experiences of low SES charity care subject/participant. A further review of the ethical guidelines shows a lack of an ethical requirement, which touches on the issue of colonisation of the research subjects. If colonisation is acknowledged in the conduct of research on IPs, then why is it non-

existent on other vulnerable groups which exhibit the same vulnerabilities as IPs do? This might be reflective of the lack of acknowledgement on the issues of colonisation, as it is an ongoing process or the mere dismissal of the core population to its existence and implication, it lacks the sensational nature of the other biomedical scandals which precipitated the formulation of the current ethical guidelines. Some of these ethical requirements act as procedural requirements such as independent review and informed consent to ensure certain values are achieved. Lastly, there is an issue of “who watches the watchmen” in the procedural application of these ethical guidelines as “experts” such as educated and trained investigators, IRBs, statisticians, ethicists and lay people are the ones who weigh the ethical permissibility of a certain research. They bring with them, in their expertise, a colonising gaze (Hooks 1992) against their research subject, which the other ethical guidelines fail to recognize. Domination, subjugation, and hierarchical nature of power and knowledge are not addressed by these ethical guidelines, which is characteristic of colonisation.

Research Subject as Currency in the Research Process

“The oppressed have been destroyed precisely because their situation has reduced them to things. In order to regain their humanity they must cease to be things and fight as men and women” (Freire 2006).

Informed consent ensures the primacy of autonomy of the individual as opposed to the utilitarian calculus of the greatest good for the greatest number. But Beauchamp (2006) clarifies the influence of the utilitarian calculus in the clinical research setting independent of autonomy: *“[...] the National Commission was very concerned throughout its work that it had become too easy in the biomedical world to use utilitarian justifications of research.”* This is illustrated in a utilitarian value, in which a moral calculus “grounded in business ethics, are used in applying cost-benefit calculations to public health policies such in the case of clinical researches” (Sharav 2013). The ethical values supporting some of the ethical guidelines set up by Emanuel and others (2000), shows the primacy of this utilitarian calculation on the risk-benefit ratio and resource allocation. A societal viewpoint has taken priority, even if informed consent and autonomy has been the focus of the different declarations as resources and researches are incorporated in utilitarian calculation of cost and benefit ratio. But this societal viewpoint should not in any way viewed through the lens of Freire’s critical theory where social awareness takes primacy. It is replete with utilitarian policies that have determined which individuals or subpopulation (especially vulnerable groups) will bear the burden of clinical research for societal benefits. The human interaction component of clinical research has been broken down to procedural and institutional bureaucratic practices, which separates the researchers from the subject/patient into

sub-human components of the whole process. When clinical research participants are considered to be variables and mere test subjects to a certain study, they are deemed as non-humans or subhumans to the colonizing gaze of the researcher (coloniser) (Nandy 1983; Hooks 1992).

Veatch (1989) contends that the ethical guidelines we follow should be viewed skeptically, as these ethical principles such as justice, autonomy, beneficence, and other ethical values are not as conclusive as they seem to be and the guidelines we apply could be less protective than they appear. More importantly, these ethical values are grounded in Western ethical values, in which, other populations might not be completely protected. Even if ethical principles such as autonomy seems to have taken primacy in the ethical guidelines, Western medical science has moved and is still moving toward utilitarianism and this process has occurred in tandem with a gradual devaluation of life (Rifkin in Ethics in embryo 1987). Thus, the Western valuation of consequentialist and non-consequentialist ethical principles should be addressed and reviewed to better cater to the needs of other populations (Olivier 1995).

The importance of considering how ethical procedures should be embedded and governed by a wider network of procedural and **cultural norms should be further discussed** (Liddell and Richards 2009). These cultural norms are beyond the scope of autonomy, beneficence, non-maleficence, justice, resource allocation, non-exploitation and conflict of interest, which govern the currently widely used ethical guidelines. There is still a room for debate on the context of colonisation, which is being applied in the conduct of scientific research involving indigenous people (Burgess and Tansey 2009). In a utilitarian calculation of cost and benefit ratio, vulnerable groups such as low SES charity care patient/subject will carry most of the burden due to their history of oppression. In terms of education, health care, accessed to resources and facilities, power imbalance, their history of colonisation prevents them from complete realization of their rights and freedom. The current ethical guidelines or principles have become a limit situation, where practices can be legitimated within the hallowed confines of the current principles even if these practices can be unethical under the lens of colonisation.

On Colonisation and Ethical Research

As discussed earlier, the implementation of ethical guidelines, such as informed consent, can act as a legitimising or procedural activity provided by persons of authority (doctors/investigators) of power over subordinates (patient/subject). This is supported by the study of Ahmad, Krupat, Asma, Fatima, Attique, and

Mahmood (2014), which shows the attitude of medical students toward their patients as more highly doctor-centered than patient-centered. The attitude “Doctors Know Best” is transferred from a teacher-doctor to the medical students where patient autonomy and confidentiality is not given importance as the focus

of the medical curriculum is disease treatment rather than doctor-patient partnership, which transfers the control of patient health to the doctors (Ahmad and others 2014). Knowledge and attitude of medical students toward clinical research is currently lacking (Wazaify, Nabulsi, Al-Khateeb and Silverman 2012). Imbalance of power through the curriculum can be as detrimental as lack of knowledge by medical students in the context of autonomy, ethical research guidelines and other related concepts, which can result to uninformed agents of power.

Medical students and teachers, a group which most likely practice clinical research, show that they are unable to answer clinical trial methodology and ethical requirements of the process (Dhodi, Thakkar, Billa, Khobragade, Sinha, and Patel 2013) as the very curriculum engenders would-be medical practitioners and clinical researchers to have a vertical doctor-patient attitude. This creates a power structure which is not bidirectional, neutral, and non-hierarchical. When power imbalance between agents of power arises, there is a possibility of existence of hierarchy of power and the subjugation of knowledge (Foucault 1972-1977). There is a totalitarian theory, which exists in the application of these ethical guidelines, where subjugated knowledge exists. Foucault argues that subjugated knowledge exists as "1) historical contents that have been buried and disguised in a functionalist coherence or formal systemization and 2) disqualified as inadequate to their task or insufficiently elaborated: naive knowledge, located low down on the hierarchy, beneath the required level of cognition or scientificity" (Foucault 1972-1977: 81-82). This is reflective of Nandy's (1983) contextualisation of colonisation in which he characterizes the colonisers as the scientific and/or the modern and the colonised as the primitive. The colonisers view that it is their responsibility and duty to modernize the primitive (colonised) through their more advanced knowledge.

In the clinical research setting, the researchers impose their more "advanced" knowledge over the rudimentary knowledge of the patient/subject. Given the context of the medical curriculum, and how this curriculum shapes medical practitioners and clinical researchers, it is contradictory to the primacy of autonomy which ethical guidelines consider having precedence over doctor/investigator paternalism. This has great implication on low SES charity care patient/subject as a group: they do not hold much power and their knowledge, beliefs, and values are subjugated in the context of a clinical research or practice. This power imbalance is not discussed in great detail in the ethical principles of the current ethical guidelines on biomedical practice and research.

The book *"Black Looks- Race and Representation"*, argues that *"the commodification of difference promotes paradigms of consumption wherein whatever difference the Other inhabits is eradicated, via exchange, by a consumer cannibalism that not only displaces the Other but denies the significance of that Other's history through a process of decontextualisation"* (Hooks 1992: 31).

Commodification should not be viewed here in the strict sense where there is an exchange of goods through economies of exchange, but vulnerable groups as the currency of the consumption process. Decontextualisation of the history of low SES charity care patient/subject lends itself to abuse, as understanding of their current status quo is not clear to authorities of power (doctor-researcher). Medical practitioners who might be involved in a clinical research practice, such as nurses, have negative attitudes toward the poor due to their misplaced character judgment of this group (Sandhurst n.d.). The attitude of physicians toward group with low socioeconomic status shows *"that health care professionals have some ambivalent feelings or attitudes toward caring for the poor and as a result it is questionable of how those attitudes affect health outcomes"* (Sandhurst n.d.: 19). This exhibits the "colonizing gaze" towards the "others" which medical practitioners harbour toward low SES group. Below is an excerpt of an interview, how a coloniser's gaze can dim a medical practitioner's understanding of the reality of a low SES research participant,

'I thought people (pause) if poor people wanted to make a difference, they could (pause) they just would have to go to school and do it and I just felt like maybe they were being lazy and that's all it was—just a case of laziness. I just thought that they maybe just needed to take a little bit more responsibility of their getting a job or, you know, doing stuff like that because where I'm from, everybody (pause) if you wanted a job you just went to the mall or you just went, you know, to the store and you got a job; but we had cars to get us to those jobs, you know, we had parents who could pick us up and take us there [.....] Well, if I have to get a job, couldn't the poor people get a job?' (Sandhurst n.d., p. 40).

By understanding the context of the coloniser's gaze and the issue of otherness, which different agents of power enforce and assume, an ethical guideline might be crafted which will best suit this group. As Freire (2006) argues, it is through reflection and action, which we will be able to advance the current situation of those who are being oppressed such as low SES charity care patient/subject. Theory without action is as lacking as action not founded in theory, as our reflection (theory) will be our guide to appropriate actions. As shown in the above passage, by having a biased understanding of the poor, decision making, attitudes and treatment of investigators creates a colonizing value. By being labeled as poor or of low SES, the current debate has altered one's place and participation in contemporary politics (Hooks 1992), in this case the participation of low SES charity care patient/subject to bioethical practices.

When membership to a group engenders someone to be commodified as a currency or resource for consumption, groups or individuals become an alternative playground for dominant groups to affirm their power (Hooks 1992). In this case, can a low SES charity care patient/subject really exercise autonomy when they are under a subjugating environment and

authority? There is a perceived notion of autonomy, as social injustices have not been addressed, autonomy acts as a banner post which does not address an injustice. The relationship or the focus of communication has slanted towards the treatment of the disease rather than viewing the patient as a human being. It seems the person is seen only as a vessel of rights and freedoms, not as an agent beyond these rights and freedoms. This is reflective of the otherness and colonisation which medical practitioners inadvertently impose on their patient/subject.

The utilitarian calculus on ethical guidelines further affirms the colonising context of subhuman treatment of the colonised. There is a perceived duty imposed on colonised groups, where resources allocated to them, it is their duty to repay this by entering in a contract to help in the pursuit of generalizable knowledge such as in clinical researches. But the history of oppression and colonisation, further subjugates them into these contracts, as such they should not be viewed as ahistorical agents rather as a product of ongoing injustices. Utilitarianism as embedded in the context of colonization legitimizes oppression as a necessary step to progress, remedy to feudalism and as a doctrine of progress (Nandy 1983). Nandy (1983) further argued that colonisation is a "political economy, which ensures a one-way flow of benefits, the subjects being the perpetual losers in a zero-sum game and the rulers the beneficiaries" (p. 31). Its utilitarian context promotes real material game and abhors the false claim of losses in social relations and psychological states (Nandy 1983). Thus, to ethically respond to vulnerable group, they should not be viewed as an ahistorical group, rather, a subpopulation which inherently and historically brings with them a culture of oppression. Mircea Eliade (in Nandy 1983: 58) argue that, *"While a modern man, though regarding himself as the result of the course of universal history, does not feel obliged to know the whole of it, the man of the archaic societies is not only obliged to remember mythical history but also to re-enact a large part of it periodically. It is here that we find the greatest difference between the man of the archaic societies and modern man: the irreversibility of events, which is the characteristic trait of History for the latter, is not a fact to the former."*

Colonisers are viewed as a modernising, dominant group, who bring with them the concept of progress while the colonised are primitive and need to be educated and have second-rate social consciousness (Nandy 1983). This is not only true to the arguments of Nandy in the context of British India but also true for vulnerable groups such as low SES charity care patients/subjects, due to their history of oppression and colonisation are viewed as a primitive group which needs to be answerable to the modern man (doctor-researcher). Some will argue that this is not far from the truth as these low SES charity care patients/subjects have low level of literacy, lower achievement, behavioral problems, dropping out of school, financial problems, health problems, negative psychological effect (Davis-Kean 1999); all indicators

created and formulated by the colonisers to legitimise their colonizing gaze. Yes, this is viewing the patients from a deficit perspective, which focuses on their weaknesses borne out of a subjugating and dominating character.

On the 9th Annual Meeting of the Report of the Global Forum on Bioethics in Research the concept of colonisation has been discussed in terms of the ethics of using Indigenous Groups as clinical research participants (Global Forum on Bioethics in Research 2008). This encompasses anthropological, sociological and biomedical researches where IPs are target groups of research. In one of the plenary session, Moana Jackson tried to frame the concept of ethical research in the unethical construct of colonisation (2008). As colonisation is an ongoing process, where research occurs in a colonising structure, it is paramount that researchers, IRBs, research institutions should act in non-colonising or decolonising ways. Jackson (2008) further argues, *"that science is not pure, it is a product of enlightenment and colonisation and it is therefore unhelpful to separate the notion of scientific method from that history, specifically in the way it relates to Indigenous People"* (p. 12). Debra Harry (2008) argues further that "current laws and policies privilege scientific, academic, and corporate interests, resulting in the misappropriation and alienation of the collective heritage of Indigenous Peoples" (p. 13). This shows that the laws, policies, and institutions that should protect the interest of minorities or the "colonised", serve the interest of scientific, academic and corporate interests.

Biomedical guidelines, even with strict adherence to ethical values such as autonomy, respect, justice, etc., are used in the justification and self-preservation of the institution and the investigators. Ethical guidelines serve to legitimize institutional requirements instead of protecting the interests of colonised groups. Harry further argues on the ongoing concept of biocolonialism, which subjugates colonised groups such as IPs, which is rooted in *"neopositivist assumption of value neutrality and in a practice of value bifurcation, which together enable it to deflect ethical and political critique,"* (Whitt 2009: 1). As a result of this practice, it expedites a culture of knowledge subjugation resulting in a legitimising rationale for biocolonial practice, which clinical research practices have assumed. Harry (2008) proposed a systemic change on research practice, such as clinical research, by viewing colonised groups as rights holders rather than stakeholders. A reflection on the difference of these terms prevents colonising nature of the research process and agents. She further argues that equitable partnerships on research, where existence of power is bidirectional, to promote respect, protect sovereignty, appropriate methodologies, is based on trust, respect and transparency (Harry 2008).

The ethical guidelines, with its ethical values, act as a limit-situation for both the researcher-medical practitioner and low SES charity care patient/subject to act within the confines of a given research. Freire (2006) argues that these limit-situations should not act

as a barrier of hopelessness, rather as a barrier to be overcome. The legitimacy and how these ethical guidelines are seen as an institutional requirement should be debated, as they promote the existence of oppression and domination of research subjects. As informed consent becomes an institutional requirement, more than a protective measure to safeguard research subjects, and the utilitarian nature of these ethical guidelines still exists, it supports the dehumanizing acts of the oppressor (research agents) towards the oppressed (subjects). This dehumanization is a result of prior situation of subjugation, which subjects the research subjects to the oppressive nature of the research practice. Fanon (1986) and Nandy (1983) qualified this dehumanization or subhumanization to the context of the primitive and the modernizing/scientific agent.

As a scientific agent or modernizing agent, it is the researcher, which has control over the primitive or the colonised. This is seen in situations in which upon completion of the informed consent, perceived or real oppression is not accounted for in vulnerable groups such as SECR charity care patients/subjects. There is no acknowledgment of the existing oppression, whether willful or not, this extends the continuing process of domination and oppression of this group. The research subjects become the currency of the research agents in their conviction to transform objects of their purchasing power. The research becomes the act of purchasing, while the research subject becomes the currency and the research results become the profit. Freire (2006) further argues that, *"We need to say no to the neoliberal fatalism that we are witnessing at the end of this century, informed by the ethics of the market, an ethics in which a minority makes most profits against the lives of the majority. In other words, those who cannot compete, die. This is a perverse ethics that, in fact, lacks ethics [.....] I do not accept. . . history as determinism. I embrace history as possibility [where] we can demystify the evil in this perverse fatalism that characterizes the neoliberal discourse in the end of this century."*

The research subject feels inferior to the researcher as he views the researcher to be the only one who knows things and runs things, here exists domination and subjugation. As the researcher and ethics committee choose the terms of engagement, through the approved research protocol, they become the actors and authors of the process and the research subjects as the objects (Freire 2006). These result in an illusion of acting through the action of the researchers by the research subject, where autonomy exists, it is only a perceived autonomy, as research subjects become mere objects of utility. Difference is the currency of production, in which this difference is often invented for the interest of social control for commodity innovation (Fanon 1986). Hence, we can assume that research is an innovative commodification of the oppressed.

Conclusion

'There is nothing noble in being superior to your fellow man; true nobility is being superior to your former self.' -Ernest Hemingway

The acknowledgment of the existence of colonisation towards IPs and the lack of it towards other groups is thematic of the primitive-scientific/modern man relationship of colonisation. As IPs remain in their primitive state, they are viewed as prone to the ethical issues which colonisation brings in the conduct of research. As the other vulnerable groups have been "modernized" and "progressed" from their primitive state, there is a mistaken belief that they are not prone to the ethical issues involving colonisation as an existing phenomenon. Kipnis addresses these types of issues in his statement, "fair entitlements of research subjects who are disadvantaged socioeconomically and in other forms should be considered to prevent tolerating unfair arrangements in the context of clinical research that we would not find acceptable elsewhere" (p. 10).

We should reflect on the argument of Freire on the supremacy of Western thought and philosophy, which pervades in the different aspects of our society. He states, *"I can go on with examples to point out how academics who argue for clarity of language not only seldom object to language that obfuscates reality, but often use the same language as part of the general acceptance that the "standard" discourse is given and should remain unproblematic. Although these academics accept the dominant standard discourse, they aggressively object to any discourse that both fractures the dominant language and bares the veiled reality in order to name it. Thus, a discourse that names it becomes, in their view, imprecise and unclear, and wholesale euphemisms such as "disadvantaged," "disenfranchised," "educational mortality," "theater of operation," "collateral damage," and "ethnic cleansing" remain unchallenged since they are part of the dominant social construction of images that are treated as unproblematic and clear"* (Freire, 2006 in p. 22).

After five decades of the development of his theory of oppression and colonisation, his arguments are still thematic of the current status quo. We cannot be ambivalent towards this philosophical theory, as it addresses legitimate bioethical issues involving biomedical and research subjects. A paradigm shift should be used in order to address issues such as colonisation, which has been a continuing ethical debate, in the application of the ethical guidelines on research.

As it might seem like it addresses the bioethical issues on any research, we have to always question institutional guidelines on how they address and resolve inherent bioethical issues. We need to always challenge the status quo, as the status quo might not represent the most ethical reality we strive to build in our society. By looking at the bioethical issue of colonisation, it lends itself to alternative discussion of bioethical permissibility of other medical procedures such as surrogacy, clinical trials in underdeveloped

countries, and other colonised groups. We have to move beyond the coloniser's gaze in the legitimization of the procedural nature of the ethical guidelines to research, which does not address the bioethical issue of colonisation and the other dimensions it brings with it. Recognition of colonization, with an implication on oppression and hierarchy of knowledge and power among agents, as an ethical guideline might lead to genuine partnership among medical practitioners, researchers and patient-participants.

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The Regulatory Regime for the Use of Embryos in Research: Braithwaite's Theory of Responsive Regulation

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Abstract

The controversies of human embryonic stem cell research is a compelling point to posit the argument that it should be stringently regulated. This paper explores the theory of responsive regulation by Professor John Braithwaite. It examines the application of his theory to the design of Australia's regulatory model in the regulation of research involving human embryos which may serve as a model for other nations to adopt. The paper also discusses the concept of tripartism, an aspect of the responsive regulatory theory, as a possible solution to the potential problem of regulatory capture/ corruption.

Introduction

While biomedical applications of stem cell research promise significant benefits, human embryonic stem cell (HESC) research raises serious ethical issues since the harvesting of stem cells from an embryo involves its destruction. The controversy of this type of research is a compelling point to argue that it should be strictly regulated. Currently, there are debates in many nations, including some Asian countries, on the legalisation and the regulation of HESC research.¹

This paper explores the theory of responsive regulation by Professor John Braithwaite, or what is termed as 'smart regulation'. It examines the application of his regulatory theory to the design of Australia's regulatory regime in the regulation of research involving embryos. It also discusses the concept of tripartism, an aspect of the responsive regulatory theory, as a possible solution to the serious potential problem of regulatory capture/ corruption. A face-to-face interview was conducted with Braithwaite to seek his views and the application of his general regulatory theory in the context of stem cell regulation.²

¹ For instance, in Malaysia, somatic cell nuclear transfer (SCNT) research may be permitted in the future. In Singapore, the research is legal and there are existing safeguards to prevent exploitation of women. But these safeguards are not as comprehensive as the Australian stringent regulation.

² Braithwaite has conducted several empirical research studies in this area, including the regulation of nursing homes and business. The interview was held on 19 October 2009 in his office at Australian National University (ANU).

Embryonic stem cells are obtained from excess in vitro fertilisation (IVF)/ assisted reproductive technology (ART) embryos and cloned embryos created through somatic cell nuclear transfer (SCNT)/ therapeutic cloning which shares the technology as the creation of Dolly, the sheep. A critical constraint is that physicians are limited by a lack of organ donors. In comparison to adult stem cells, embryonic stem cells are much easier to identify, isolate, maintain and grow in the laboratory. They are also more versatile than adult stem cells. As pluripotent cells, they have the capacity to form each cell type in the body to create skin, bones, organs and other body parts that patients with injuries or illnesses in need of transplants might need to receive. Embryonic stem cells have unique properties; they are unspecialised and able to divide as well as renew themselves for long periods. These cells will permit the growth of required tissue when it is needed.

There are scientists who regard HESC research as the epitome of stem cell research. In 2013, Shoukhrat Mitalipov and his team at the Oregon Health & Science University and the Oregon National Primate Research Center accomplished a scientific first by creating embryonic stem cells from cloned human embryos through SCNT research using cells from infants. In 2014, researchers at the Research Institute for Stem Cell Research at CHA Health Systems in Los Angeles had produced stem cells using SCNT, from adults, bringing them closer to developing patient-specific lines of cells.

The Importance of Regulating Ethically Controversial Research

The first question to ask is whether it is necessary to regulate HESC research. It might be argued that it is preferable to adopt a minimum regulation or to leave the research as completely unregulated. In general, scientists may prefer free and uninhibited research.

There are respectable individuals who argue in favour of adopting the regulation. Francis Fukuyama asserts that it is crucial to regulate biotechnology (Fukuyama, 2002). He is concerned that unregulated biotechnology poses an insidious threat to society's way of life and compromises human dignity.³ He states that 'the people in Brave New World may be healthy and happy, but they have ceased to be human beings. They no longer struggle, aspire, love, feel pain, make difficult choices, have families or do any of the things that we traditionally associate with being human. They no longer have the characteristics that give us human dignity' (Fukuyama, 2002). He explains that there is a grave concern that, ultimately, biotechnology may cause society to lose its humanity, which is an essential quality that has underpinned its sense of who they are (Fukuyama, 2002). Roger Brownsword also

³ Fukuyama explained that on one extreme of the continuum is nuclear technology which is extremely dangerous and on the other extreme is information technology (IT) which is relatively benign. Biotechnology lies in between the two extremes.

supports the need for regulation, stating, 'no regulation is hardly a serious option and there is surely little virtue in leaving eugenics to the play of subjective preference and the market ... if we accept the deeper implications of a liberal eugenics, such an abdication of regulatory responsibility is likely to have highly corrosive consequences ... the dilemmas associated with the regulation of human genetics must be confronted' (Brownsword, 2004).⁴

Michael Kirby makes a strong case for adopting a regulation, especially for controversial research (Kirby, 2008).⁵ He refers to reproductive cloning where he asserts that for the law to be silent about the activity is to provide a green light to conduct experiments in the technology. He states that nothing then would restrain the scientists except for their ethics, their religious beliefs, the availability of research funding and institutional ethics clearance requirements. Without regulation to prohibit or regulate an activity, scientists may choose to conduct controversial experiments because of interest and or curiosity. Kirby says that regulatory inaction is a decision; he warns that the absence of regulation can be interpreted to mean that the society has made a decision to allow the technological advances to arise without impediment. He asserts that while 'proponents of technological innovation have often favoured containment of law and a libertarian approach to the development of technology, yet most lawyers recognise that there are limits' (Kirby, 2008). Kirby is also concerned that overregulation might be worse than no regulation at all as it may impose burdensome constraints on scientists. He stresses that 'limits must be clearly expressed and upheld in an effective way' (Kirby, 2008).

The regulation of scientific research is not a new subject. In biotechnology,⁶ there are countries which are enacting regulatory instruments to regulate controversial areas of research. In Australia, the *Gene Technology Act 2000* (Cth) was passed to regulate research on genetically modified organisms (GMOs), the objective is to protect the health and safety of people and also to protect the environment. In Australia, the decision has already been taken to pass legislation to regulate research involving human embryos primarily because law promotes certainty and clarifies what is permitted for stem cell scientists. To quote a report (Human Cloning: Scientific, Ethical and

Regulatory Aspects of Human Cloning and Stem Cell Research/ Andrews Report): 'We owe it to the scientists to try and clarify, through legislation, those circumstances in which procedures may be acceptable ... and those cases in which a line may be drawn ...'⁷ Accordingly, enacting laws to regulate HESC research will provide higher likelihood of clear boundaries, scope and protections to stem cell scientists. It also ensures transparency and accountability.

Achieving Regulatory Effectiveness

It is interesting to note that Brownsword recommends the application of Braithwaite's responsive regulatory theory to achieve regulatory effectiveness.⁸ He asserts that, "There is no point in reinventing the wheel ... We do have some general regulatory intelligence. It is not as though observers of the regulatory process have detected no recurring patterns (relatively speaking) in regulatory failure and regulatory success ... we can carry forward the principal insights of smart regulatory theory, namely that traditional criminal law interventions cannot be counted on to control in the way that regulators intend, that regulators have at their disposal a range of instruments that might be deployed to channel and control conduct and that regulators would do well to seek out the particular combination of instruments that most effectively promote their particular regulatory purposes. While these insights are valuable in steering regulators away from interventions that are likely to be futile or even counterproductive, we are ... short of a comprehensive and reliable regulatory jurisprudence (with settled precedents) pointing to the particular combinations of instruments that are appropriate for particular cases" (Brownsword, 2008).

Brownsword identified the primary challenges of regulating innovative technologies and one of them was the problem of attaining regulatory effectiveness (Brownsword, 2008). In regulating new technologies, it is essential that regulators bear in mind the difficulties that they may encounter. He warns that unless these challenges are adequately addressed, the regulatory environment is defective, 'as opposed to a regulatory environment that supports the development, application and exploitation of technologies that will contribute to such an overarching purpose, an environment properly geared for risk management and benefit sharing' (Brownsword & Somsen, 2009). Accordingly, to establish an effective regulatory framework for emerging technologies, the regulators must first recognise the difficulties likely to be faced and then attempt to design and sustain a regulatory environment that is effective.

⁴ Roger Brownsword (Kings College London) is a bioethicist and a leading scholar on issues of technology, ethics and law.

⁵ Michael Kirby is a retired High Court judge.

⁶ Biotechnology is described as using living things, including plants and animals, to create products or to perform tasks for human beings. Over time, biotechnology has formed the basis of learning about human diseases and the development of medical treatments. It has led the way to a new era in health care with the development of improved methods for detecting, preventing and treating diseases. These include the development of new diagnostic and therapeutic tools, DNA profiling, cloning and stem cells.

⁷ See 57-58 of Andrews Report where the committee reported that they agreed with Professor Donald Chalmers' view to introduce legislation.

⁸ There was also an interview conducted with Brownsword held on 18 November 2009 in his office in the law faculty, Kings College London.

Regulators achieve regulatory effectiveness when their intervention works and is fit for purpose i.e., it needs 'to be beyond reproach ... a regulatory intervention must be backed by legitimate regulatory purposes, and the regulatory means employed must be both morally clean and effective' (Brownsword, 2008) or else the regulatory environment is deficient.

The Responsive Regulatory Theory⁹

An effective regulatory framework for HESC research should be responsive. The theory of responsive regulation was conceptualised by Professor Ian Ayres and Professor John Braithwaite in 1992 (Ayres & Braithwaite, 1992). This theory proposes that 'regulators should be responsive to the conduct of [regulatees] [before] deciding whether a more or less interventionist response is needed' (Braithwaite, 2008). The first response to proscribed behaviour is to determine how effectively individuals or corporations self-regulate before deciding whether to escalate intervention. Giving primacy to less invasive responses facilitates this approach¹⁰ and 'attempts to solve the puzzle of when to punish and when to persuade.'

The most distinctive part of the responsive regulation is the Braithwaite's regulatory pyramid (see Figure 1) with every increment step increasingly demanding in its sanctions. The pyramid illustrates the idea that less punitive measures should be the reaction of the first instance. At the lowest rung of the pyramid, self-compliance is encouraged. The broad foundation of the pyramid represents most of the cases which are dealt with informally, restorative dialogue-based approach. They are not punitive responses; they are based on persuasion and self-regulation. The narrowing towards the top of the pyramid illustrates the increasingly fewer cases handled by progressively more formal means.

Moving up the pyramid, the regulations are becoming more demanding in their sanctions. The inexorability of escalation to punitive responses is the key to influencing human behaviour. Regulators will be able to move up and down the pyramid to access the appropriate level of regulation necessary.

Beginning at the base of the pyramid, attempts are made to encourage compliance with the law by persuasion. If this does not materialise, the next step is to issue a warning; if this does not lead to compliance, civil monetary penalties are imposed. If this fails, criminal prosecution ensues and penalties such as fine will be imposed, if this fails, the licence to operate is suspended and this fails, arriving at the apex of the

pyramid, the licence to do business is revoked and the business will cease.

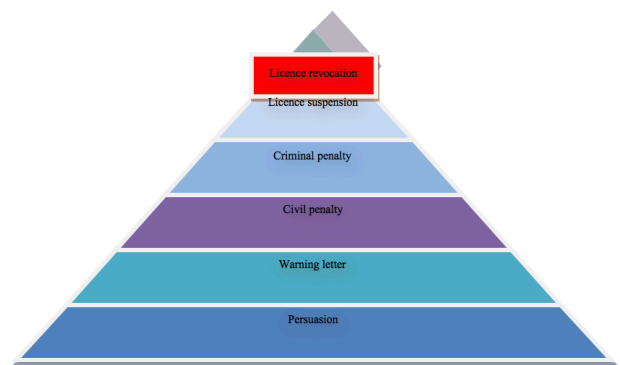


Figure 1: An example of Braithwaite's enforcement pyramid in the context of a business

According to responsive regulatory theory, a 'spectrum of punishment [is] threatening in the background but never threatened in the foreground' (Braithwaite, 2008). The theory claims that if persuasion is to work, stiffer forms of consequences must loom as a real and likely threat. The primary issue is that the peak of the enforcement pyramid creates downward pressure that causes most of the action to occur at the bottom of the pyramid, that is, in the realms of persuasion and self-regulation (Braithwaite, 1990-1991). The existence of the ability to get as tough as is necessary can bring into existence a culture that is voluntaristic and less litigious. Braithwaite asserts that if the top of the pyramid is removed, there would be fewer prospects of self-regulation and persuasion as an alternative to punishment. The greater the heights of punitiveness to which a regulatory agency can escalate, the greater its ability to push regulation down to the bottom of the enforcement pyramid. A truncated pyramid with a truncated range of escalations will exert less downward pressure to keep regulation at its base than a taller pyramid whereas a tall enforcement pyramid can be used to apply considerable pressure from the heights of its peak to promote voluntary compliance.

Braithwaite refers to the regulatory agencies as 'the Benign Big Guns that walk softly while carrying very big sticks' (Braithwaite, 1990-1991); while regulators indeed have powers, they seldom use the power of criminal prosecution. Compliance with the law is optimised by regulation that is both robust and forgiving. Forgiveness is advocated for its importance in building commitment to comply in future and punishment is about deterrence. As Braithwaite states, 'Paradoxically, the bigger and the more various are the sticks, the more regulators will achieve success by speaking softly'.

It is noted that the theory of responsive regulation might not be appropriate in some regulatory arenas. Ayres and Braithwaite explain that the theory is 'not a clearly defined program or a set of prescriptions concerning the best way to regulate' and therefore, the theory should not be mechanically applied as the appropriate strategy to be adopted would 'depend on the context, regulatory culture and history'.

⁹ This section relies on John Braithwaite, *Regulatory Capitalism*, Edward Edgar Publishing, 2008, 88-139.

¹⁰ Braithwaite explains that what motivated him and Ayres to formulate this theory is due to the frustration with the 'see sawing' in policy making between two groups of people; on one hand, a group who argues that business people only understand the bottom line and therefore must be punished for lawbreaking and on the other hand, a group who claims that business people are responsible people who can be persuaded to comply with the law.

(Braithwaite, 1992). It is acknowledged that the theory of responsive regulation is an approach designed in developed countries. Also, it is recognised that a limitation that the developing world faces is the lack of capacities necessary to make responsive regulation work effectively compared to wealthy societies. However, Braithwaite argues, "Responsive regulation deals with the fact that no government can enforce laws. It is useful for thinking about regulation in developing countries with weak enforcement abilities" (Braithwaite, 2006). The theory of responsive regulation is relevant and applies in developed and developing economies.

Australia's Regulatory Scheme on Research Involving Human Embryos and the Application of the Responsive Regulatory Theory

An essential characteristic of Australia's regulatory regime over HESC research is its stringent statutory licensing scheme. The *Research Involving Human Embryos Act 2002* (RIHE Act 2002) establishes a national licensing system where scientists must be licensed for each research project that involves the use of a human embryo. The aim of the Act is to allow research on embryos but only in limited circumstances. Its main feature is the licensing regime for the use of 'excess' assisted reproductive technology (ART) embryos and SCNT embryos as well. The Act creates some offences relating to the utilization of the human embryos without a licence. It is an offence to use an embryo that is not an excess ART embryo or SCNT embryo (Section 11) and to breach a licence condition (Section 12). The seriousness with which the legislature regards these offences is reflected in the penalties with a maximum of five years' imprisonment.

The Act establishes the Embryo Research Licensing Committee (Section 13) whose primary job is to license the use of excess ART embryos and SCNT embryos in research (Section 20). There are two stages to the issue of a licence. Section 21(3) *RIHE Act 2002* states that the licensing committee must not issue the licence unless it is satisfied with the fulfilment of various conditions, one of which is that the applicant must have obtained approval for the project by the Human Research Ethics Committee, in accordance with and acting in compliance with the *National Statement on Ethical Conduct in Human Research* (2007) (*National Statement 2007*). Secondly, section 21(4) *RIHE Act 2002* provides that in deciding where to issue the licence, the licensing committee is directed to consider various matters including 'any relevant guidelines ... published by the CEO of the National Health and Medical Research Council (NHMRC) ...' and 'HREC's [research ethics committee's] assessment of the application ...'. The NHMRC guidelines accompany the legislation which lay down the steps that researchers should comply. While these guidelines are not legally enforceable, failure to follow them is likely to lead to non-issuance of a licence to conduct the research. The licensing committee will not issue a licence to a scientist who intends to embark SCNT research unless his/ her research proposed in

the application is evaluated and approved by a research ethics committee. This committee will make sure that the researcher has acted in accordance and compliance with the *National Statement 2007*. The research ethics committee's approval of the application is a pre-requisite for the issuing of a licence.

The key features and operations of the Embryo Research Licensing Committee of the National Health and Medical Research Council (NHMRC) (LC) include the committee's membership, duties, powers, operations including the issue of licence, the imposition of licence conditions, variation/ suspension/ revocation of licence and monitoring compliance, reviews and appeals by applicant for licences, offences under the Act, transparency and cost recovery mechanism. This is the major role this regulatory authority has performed in the effective regulation of research involving human embryos in Australia since 2003 and this continued after the *Amendment Act 2006* was passed. There is general support for the necessity of the oversight of embryo and stem cell research. The LC fulfils a valuable role in this process based on submissions in the Lockhart review. These favourable submissions influenced Recommendations 34, 35 and 38, which provided for the continuity of the LC as the regulatory body in this area of enforcement.

Pyramid design is described as a creative and deliberative activity (Braithwaite, 2006). 'Regulators who think responsively tend to create different types of pyramids for various sorts of situations (Braithwaite, 2006). The pyramid of regulatory strategies is illustrated in Figure 2 below.

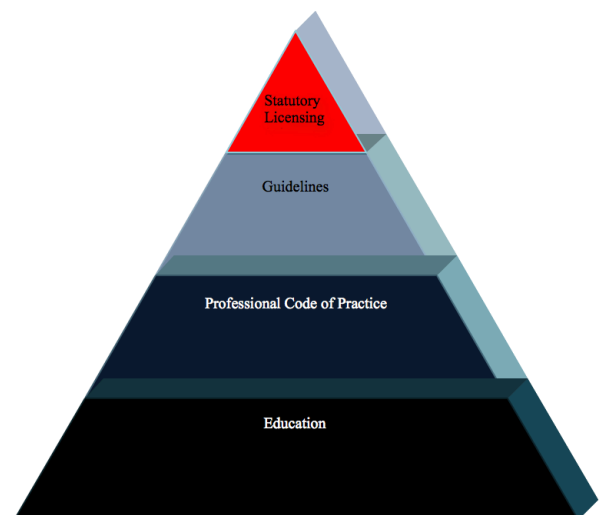


Figure 2: A pyramid of regulatory strategies to regulate HESC research

At the bottom of the pyramid is education. Through this strategy, awareness is created among stem cell scientists about the importance of observing high ethical standards while embarking HESC research as well as the results of non-compliance with the law. The Australian regulatory framework incorporates this critical aspect; it is based on the concept of 'cooperative compliance' where licence holders are encouraged to cooperate with the NHMRC to comply

with the legislation. In addition to education, the emphasis is also placed on communication; collectively, these will create and promote awareness of the responsibilities of both licence-holders and inspectors. A key mechanism for raising awareness is through information exchange visits, which were provided to researchers, human research ethics committee members and other groups. Also, information is provided through seminars, workshops, websites and publications. These activities may deter scientists from breaching the law.

On the next level of the pyramid is the professional Code of Practice/ industry self-regulation, the objective being to give guidance and support as well as advice to scientists. Professional bodies and institutions should be encouraged to adopt industry self-regulation as it sets industry standards for compliance. However, this paper notes that a reservation of the model of self-regulation is that it may be seen as a licence for self-interested regulatory activity, that is, the industry may act in ways that suit its interests and sets regulatory standards as long as it is happy to comply with those criteria.

Higher up on the pyramid is the Guidelines scheme, also known as soft law, created by government agencies.¹¹ Guidelines are particularly useful in the regulation of new technologies. They are flexible and may be amended as needed. Changes can be done gradually, focusing on areas that arise as fresh discoveries are made.¹² Finally, at the apex of the pyramid is a statutory licensing scheme where restrictive research on embryos is allowed by statute and criminal offences apply where the activity is pursued without a valid licence.¹³

The regulatory architects in Australia use Braithwaite's theory of regulation. Its regulatory design illustrates the various rungs of the pyramid of regulatory instruments incorporating a mix of different strategies namely, education, guidelines and strict statutory licensing system. Smart regulation explores many avenues. The evolving responsive Australian regulatory regime, incorporating a combination of the statutory licensing scheme, adherence to NHMRC guidelines and education promoting awareness of responsibilities, backed by monitoring and inspection system for facilitating monitoring compliance with the legislation, achieves regulatory effectiveness. Education visits to research centres by the LC create awareness among researchers of their responsibilities under the Acts. The strict criteria that the LC must adhere to in issuing licenses, only where it is satisfied that the proposed activity has been considered and approved by an HREC acting in compliance with the

NHMRC's *National Statement*.¹⁴ The LC must also have regard to relevant guidelines issued by the NHMRC.¹⁵

To date, there has been no finding of non-compliance by Australian stem cell scientists and hence, there have been no prosecutions. This point illustrates the success of the Australian regulatory system governing research involving human embryos and thus, it is a model that other nations may consider emulating.

The Strengths-Based Pyramid

It is also useful to explore Braithwaite's second pyramid which is the 'strengths-based pyramid' as illustrated in figure 3. It is a pyramid of responses to both individuals and organisations. This pyramid of support promotes a virtue whereas the pyramid of regulatory strategies restrains vice. It has characteristics of the provisions of incentives instead of the imposition of punishments. As it progresses upwards, it moves to targeting progressively bigger rewards on progressively smaller target groups. Beginning at the bottom, strategies are minimally interventionist and minimally costly, yet they have the relevance to the broadest community (Braithwaite, 2008).

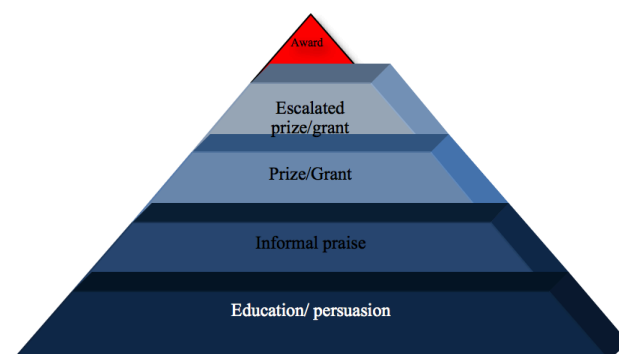


Figure 3: A possible approach to a Braithwaite's pyramid of strengths-based pyramid to motivate conduct

The responsive regulatory theory suggests that 'regulators should operate with a cooperative default approach' (Brownsword, 2008) and try to attain win-win relationships with the regulatees. They will perform 'well to respond to non-compliance in a way that leaves room for escalating sanctions, for flexibility, and for sensitivity to the nature and character of particular regulatees' (Brownsword, 2008).

With the strengths-based pyramid model (Figure 3), scientists are motivated to be compliant with regulations. At the bottom of the pyramid, through education, researchers are informed and motivated to conduct research while observing high ethical standards. On the next level is receiving a praise and not everyone is singled out for special praise. This is followed by winning prize/ research grant and again

¹¹ For instance, NHMRC guidelines in Australia.

¹² Countries that have adopted national guidelines scheme as their regulatory model include USA, Japan, India, China, Spain and Malaysia.

¹³ Nations which have statutory licensing scheme include UK, Sweden, New Zealand, Canada, Finland, Greece, Israel, the Netherlands, Singapore, South Korea, the American states of California and New Jersey.

¹⁴ *Research Involving Human Embryos Act 2002* (Cth) , s21(3)(c).

¹⁵ *Ibid* s21(4)(c).

not every scientist will get the award. The next rung is 'escalated' prize/ award and few will obtain, for instance, a \$1m grant. At the apex of the pyramid, even fewer will receive an award such as the Nobel prize or being conferred knighthood or being named as the 'Person of The Year' and getting a cash prize.

It is noted that both pyramids are complementary. A regulatory system, which includes both regulatory and strengths-based pyramids, is effective as it has a combination of instruments that promote the regulatory purposes with a spectre of punishment in the background. Thus, they have the effect of controlling the conduct of scientists. As Braithwaite states, it is paramount to adopt a mix of support and sanctions.¹⁶

Regulatory Capture and Tripartism

Brownsword has expressed his concern that regulatory agencies may be 'captured'/ bribed by some powerful and influential regulatees (Brownsword, 2008). Regulatory policy that fosters cooperation between the regulator and the regulatee could even encourage corruption. This is especially true where relationships between the parties are ongoing and encounters are repeatedly made by the same regulator. Corrupt dealings then become more tempting to both sides.

A method to achieve regulatory effectiveness is to assign inspectors to monitor the licensees' compliance with the law. Brownsword agrees that the inspectorate system might meet regulatory effectiveness as it is a natural feature of a regulatory regime. Having set the standard, the regulators then have to monitor and an inspection is what they do. Then the question is whether this will guarantee compliance to which the answer is no.¹⁷ He cautions that an inspection system is no guarantee of conformity concerning some hypothetical scenarios.¹⁸ Where the regulatory regime requires the inspector to provide notice before the day of the examination, as opposed to making random visits, this announcement will enable preparations to be carried out before the audit is conducted. Also, where regulators face limited resources, the frequency of inspections could be reduced. Where regular inspections are conducted, a cosy relationship between the inspector and the researcher might even develop and the inspector is captured by the regulatee. If it is not completely transparent and unaccountable, the regulatory authority is prone to be captured by its licensees from whom the body derives its funds. While these scenarios suggest that monitoring compliance by inspectors does not guarantee regulatory effectiveness, it is nevertheless a natural feature and significant to include such monitoring as part of the package of the regulatory system.

Braithwaite explains that any system could be corrupted but some are harder to corrupt than others. He refers to examples where there are opportunities for corruption and says, 'Elections could be fixed. You

can corrupt the electoral officer and get him to count the votes wrongly' and he also gives the example of the grant of an Oscar academy award where every member of the academy gets a vote as to who shall win the Oscar, so there's the possibility of corruption.¹⁹

As a possible solution to the severe risk of regulatory capture/ corruption, Braithwaite advocates the concept of tripartism, a process involving a third player in the regulatory process, for example, public interest groups (Ayres & Braithwaite, 1992). It encourages the participation of these groups by giving them access to the information available to the regulator, a seat at the negotiating table with the regulatory agency and regulate, and the authority to sue or prosecute. As Braithwaite explains, "Solutions to the problems of capture and corruption - limiting discretion, multiple industry rather than single industry, agency jurisdiction and rotating personnel- inhibit the evolution of cooperation" (Ayres & Braithwaite, 1992).

As an illustration of the concept of tripartism, Braithwaite refers to the example of the issue of a grant. He explains, "When you have a licensing board that gives grant, the committee does it rather than a bureaucracy and you have representatives. Tripartism, that is what most countries do. The government gives out research grants to universities but people who make recommendations to government are people who are experts from industry, from universities, from the government and they sit down as a committee to make a collective decision. It's much harder to bribe a committee than it is to an individual bureaucrat. If it's a bureaucracy giving out a grant, then all you have to do is to bribe the head of bureaucracy ... So you just have to corrupt one person but if it's a committee with people from outside the bureaucracy that are giving out the grants, then you can still bribe the committee but it's hard. One member of the committee isn't open to being bribed and blows the whistle on all the others. He/ she might find it morally offensive to take a bribe. And those who take a bribe fear that they may be in trouble. So the committee are protected against bribery just like juries in criminal cases. Juries are good institutions and one of them is that it's always easier to bribe a single judge than to bribe the whole jury. The judges are repeat players so they build a relationship and use that. If you're an organised crime group, you build that relationship with the judge. You can bribe that one judge on multiple occasions. The organised crime group makes that investment with the judge. Whereas with juries, this is the only case that they sit on with their whole lives and the investment in building that relationship does not bring much return. So it's harder to bribe a committee. The solution connects with tripartism that is having the third or fourth party involved in the process".²⁰

¹⁹ In an interview with Braithwaite.

²⁰ In the interview with Braithwaite, he referred to Indonesia's independent Corruption Eradication Commission/ Komisi Pemberantasan Korupsi (KPK) which he thinks was effective in controlling corruption in the country in the period 2005 -2008 and he also made brief reference of the success of the Hong Kong model.

¹⁶ In an interview with Braithwaite.

¹⁷ In an interview with Brownsword.

¹⁸ Ibid.

In Australia, the composition of its NHMRC Licensing Committee comprises professionals from a diverse background. The selection of the committee prescribed in the legislation reflects this. It requires that board members be drawn from a range of areas of expertise which include expertise in research ethics, public health research, biotechnology law, embryology, consumer issues relating to assisted reproductive technology, consumer health issues related to disability and disease and regulation of assisted reproductive technology. Thus, tripartism is an effective solution to the potential problem of regulatory capture/ corruption and it is, therefore, important to have multi-players in the field.

Conclusion

It is critical that the regulation is based upon good science as opposed to basing judgments 'upon assumptions, religious dogma, intuitive beliefs or popular opinion' (Kirby, 2008).²¹ Braithwaite's responsive regulatory theory is useful and influential in the design of an effective regulatory framework to regulate HESC research. With such tight regulation over controversial research, this has the effect of allaying public concerns and restoring confidence.

Regulatory effectiveness could be attained when regulators apply Braithwaite's theory, which suggests a mix of different regulatory strategies. With the pyramid of strategies, the emotional economy of shame and the strengths-based pyramid, emotional economy of pride, there is a range of instruments that inflict punishments as well as provide incentives. These devices are employed to channel/ control the conduct of scientists involved in the field of HESC research. They will promote the regulatory purposes and the framework has a spectre of punishment in the background. A regulatory architecture that comprises a collective mix of regulatory instruments leads to regulatory effectiveness, as argued by Brownsword.

Accordingly, in nations which are contemplating regulating the controversial HESC research, the design of the regulatory framework based on Braithwaite's responsive regulatory model, comprising the two pyramids, is recommended for adoption. They could consider the various specific provisions of the Australian regulatory framework on cloning and stem cell research and its strict regulatory regime is an excellent model for other countries to emulate.

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²¹ Kirby explains that countries that have been most successful in responding to HIV/ AIDS are those that have observed this important point.

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