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Editorial: Reflection on Life Ethics

The theme of life ethics is explored through the 7 papers in this issue of *EJAIB*. Bang-ook Jun revisits a bone marrow donation that occurred two decades ago in Korea, and questions the ethics of the then Commander in Chief of the Military, insisting on all soldiers having a test for compatibility as a bone marrow donor. It is claimed that there was a lack of freedom of choice, with implications for high level campaigns for donors that are sometimes made. Masayuki Kodama reports on the recent legislative moves in India and Thailand, two havens for commercial surrogacy trade, that have developed laws to restrict access to surrogacy services in those countries to those who are nationals, or in a real relationship with a national.

Sumaira Khowaja-Punjwani explores some issues including vulnerability in Pakistan and in the developing world in general, that researchers and ethics committees should read. Rhyddhi Chakraborty examines equity in the Indian National Tuberculosis (TB) Prevention Program, which has implications for the policies in other countries as well. More attention should be placed on TB prevention, which is often neglected. Hannah Holitzki and Gregor Wolbring use a literature analysis to examine the frequency of key words in papers published in responsible innovation.

There are two papers on bioethics/moral education, Lara López-Hernáez and Carmen Sabater Fernández found gender differences in emotional skills in Spanish teacher trainees, with implications for the reform of teacher training. They used the AURE instrument to examine moral reasoning of teachers and views of life. Manjae Kim and Kyung-Suk Sung review bioethics curriculum in Korea at junior and senior high school and two universities, calling for increased attention to bioethics. They recommend including bioethics and life ethics education, and also the UNESCO Bioethics Curriculum.

The 17th Asian Bioethics Conference of the Asian Bioethics Association (ABA), ABC17, will be held in UGM, Jogyakarta, Indonesia, 14-17 November, preceded by a National Bioethics Meeting which also welcomes all participants.

- Darryl Macer

Reflection on the bone marrow donation to Sung-Duk Bauman[1]

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Abstract

Sung-Duk Bauman was born in Korea and adopted to an American family. Later, he was diagnosed with chronic myelogenous leukemia. His family began to search for potential donors having compatible bone marrow that exactly matched to his bone-marrow type. After broadcasting a touching documentary on this tissue search, a national campaign to look for donors swept Korea. The Commander-in-Chief ordered the military to find the match in an army donor and the transplant was successfully done.

Twenty years on, upon close examination of the supposed altruistic donation, several ethical issues now emerged. First, the donation was mandatory and not voluntary on the part of the army donor. Second, the Ministry of National Defense disclosed the identity of the donor before the family consent for transplant was given. Third, the information consent process for the donor or his family was also improper. Fourth, the medical staff failed to prepare a safeguard for the donor. This paper insists on free and voluntary donation of human tissue and/or organ, and not forced, commanded or mandated donation.

Key words: Transplantation, tissue/organ donation, informed consent, donor's right

Introduction

Sung-Duk Bauman was a U.S. Air Force Cadet, born in Korea and adopted at the age of 3 to an American family. Before graduation, he was diagnosed with chronic myelogenous leukemia. He could not have survived five years if someone had not donated compatible bone-marrow to cure his disease. His family began to search for potential donors including his biological parents and siblings. There was a narrow chance to find the compatible bone marrow that exactly matched to his bone-marrow type. After failing to get information on Bauman's biological parents and siblings, the Korean media made this a touching tissue donation documentary, with one producer saying: *"His country abandoned him once. We must not do it again."* A national campaign to look for a donor soon ensued with 20 civic and religious organizations participating and 7,000 bone-marrow registry entries. The Commander-in-Chief ordered the military to register as potential donors and it was from their ranks that a match was found and the transplant was successfully done.

Twenty years on, upon close examination of the supposed altruistic donation, several ethical issues now emerge.

To volunteer or to be volunteered?

First, the donation was mandatory and not voluntary on the part of the army donor. The donor was in military service, where soldiers are situated within ranks.[2] Soldiers are often coerced "to be volunteered" to sacrifice even their lives for the common good. Though he might not have sufficient intention to give his bone marrow to others, it was probably difficult for him to decline to be tested for initial compatibility against the order of the Commander-in-Chief. No one knows for sure whether he joined the registry voluntarily or not.

Cheyette (2000) categorically divided donors into the donor who is altruistic, remained anonymous and the donor who decides to donate in response to internal or external pressure. And the donor decides to donate can be divided into two groups.[3]

[1] Part of this paper was presented in 16th Asian Bioethics Conference held at St. Paul University Quezon City, Philippines on November 8, 2015.

[2] See Goodwin (2007) (defending children donors right against compelled donation, "Children are uniquely situated within families, where the power relationships are vertical and their status resides at the bottom" and "youth are coerced into "volunteering" for the sake of "saving" their tribes, governments, or communities; and such sacrifices for the common good can demand an enormous social price. The moral value of those types sacrifice does not pale in the face of individualism. There are some sacrifices that should not come with applause, lest we encourage unsound behaviors for which the costs may be socially and legally incalculable or morally unjustifiable. Rather, we must be guided by critical thinking as it relates to altruism, There are some sacrifices that should not come with applause, lest we encourage unsound behaviors for which the costs may be socially and legally incalculable or morally unjustifiable. Rather, we must be guided by critical thinking as it relates to altruism. Individuals who decide to donate organs fall into two primary groups: those who donate in response to a sense of moral obligation and those who donate in response to pressure from the society. Generally, when adults decide to donate in response to a sense of moral obligation-that is, on the basis of an internal motivation-they experience their participation as voluntary and generally feel good about their decision. While the society member's need for the organ triggers the donor's feeling of moral obligation, the donation itself is driven by the need to satisfy the feeling of obligation").

[3] See Cheyette (2000) ("Individuals who decide to donate organs fall into two primary groups: those who donate in response to a sense of moral obligation and those who donate in response to pressure from the society. Generally, when adult decide to donate in response to a sense of moral obligation-that is, on the basis of an internal motivation-they experience their participation as voluntary and generally feel good about their decision. While the society member's need for the organ triggers the donor's feeling of moral obligation, the donation itself is driven by the need to satisfy the feeling of obligation. The second group of adults decides to donate in response to pressure from the society. This pressure can range from subtle situational pressure, to messages as blatant as: "if you don't donate, s/he will die." Whereas moral

In this case, the bone-marrow tissue was harvested rather than donated.[4]

Urgency and disclosure of the situation results in the adult donor being pressured to make an immediate decision, while for the vulnerable donor, the situation results in a rushed proceeding in which the donor's interests go unprotected (Cheyette, 2000).

The donor who is volunteered may be more likely to experience psychological or physical trauma than the donor who steps forward as a mature and competent volunteer (Cheyette, 2000). One of the Korean media reported that the potential donor was in a psychiatrically unstable condition before the surgery, and the medical team had to postpone the whole schedule (Jang, 1996).

Donor's identity disclosed without consent

Second, the Ministry of National Defense disclosed the identity of the donor before the family consent for transplant was given. The participants in bone marrow registries usually remain anonymous, though the donor and recipient's identities may be disclosed with both parties' consent (Cheyette, 2000). Soon after finding the compatible bone-marrow, the Ministry of National Defense spokesman announced that "The compatible donor is a 23-year-old army sergeant surnamed Soh. The consent of his family has yet to be ascertained."

While the donor's identity was disclosed, he had to be volunteered in response to pressure from the society. With directed donation by a nation-wide campaign to save Sung-duk Bauman, worries could arise about the intense pressure put on sergeant Soh to donate, leading someone who might be reluctant to do so, to feel coerced (Truog, 2005).

Directed donation to a stranger (in this case, a celebrity) raises more additional ethical questions[5] (Truog, 2005).

Improper consent process

Third, the consent process for the donor or his family was also improper. As the identity of potential donor was disclosed, the surgery should be done in a hurry on the part of the Ministry of National Defense whether donor and/or his family gave proper consent or not. It was reported that his family once refused to give the consent, but finally they surrendered. It seems not an informed consent process but persuasion that enabled them to give their agreement.[6]

Also before the consent, the donor should be fully provided with the information that (1) the risk that death or serious injury will result from the harvest; (2) the temporary or permanent physical changes that the harvest will cause; and (3) the overall level of surgical complication or invasiveness of the procedure (Cheyette, 2000).[7]

Failure to prepare a safeguard

Fourth, the medical staff failed to prepare a safeguard for the donor. It is possible that any vulnerable individual, including a soldier, could be coerced into donating a tissue or an organ. When the donor is under an extremely coerced condition, the transplantation centers are typically willing to identify a plausible medical excuse, so that the person can escape the situation gracefully (Truog, 2005).[8]

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obligation can be properly called an internal motivation, these pressures are external and can be quite intense. Even when the pressure is not overt, the treat of society sanctions may be coercive to the point where society members feel that they truly have no choice. More than half of the kidney donors in one study group were subjected to pressure that researchers felt had a "compulsory quality"").

[4] See Cheyette (2000) ("Organs are "donated" by competent adults who voluntarily and altruistically consent to give what is sometimes called "the greatest gift." Competent adults are under no compulsion to submit to organ harvests for the benefit of third parties. Notwithstanding the internal and external pressures on society members to volunteer; competent adult may decide that for whatever reason, they are unwilling to step forward. Besides, organs are "harvested" from living individual who are unable to give a full competent, valid consent because of their age, mental illness or weak societal position. It is this latter methods of obtaining organs that poses the ethical dilemma").

[5] See Troug (2005) ("This type of donation usually occurs when a patient's appeal for an organ publicly, on television or over social network services. Such appeal is not illegal, but it has been strongly discouraged by the transplantation community. Two central objections are that the practice ignores waitlist and patient who have the most compelling stories and the means to advertise their plight tend to be the ones who get the organs - rather than those most in need. This strikes some ethicists as unfair").

[6] See Korea Times (1996) ("[Sgt.] Soh said during an interview "I thank my parents for allowing me to donate my bone marrow."…… Soh's parents were reluctant at first to allow their son to donate part of his body but readily agreed after being told about Bauman's plight").

[7] See Cheyette (2000) ("After undergoing tissue typing, a bone marrow harvest must be done under general anesthesia so the marrow can be extracted via multiple punctures in the pelvic area with a rigid needle screwed through the bone. It takes approximately half an hour and upwards of 200 taps to extract one liter of bone marrow fluid from an adult"). And see also Goodwin (2007) ("Such invasive procedures poses health risks, including the potential for complications with anesthesia, difficulties during the operation, the need for possible post-operative blood transfusion, and other problems unique to the particular type of harvesting").

[8] See Israni et al. (2004) ("Such coercion has been described when vulnerable society members are chosen based on blood type and cross matching. Therefore donors should be 'competent, medically and psychologically stable, and fully informed of risks and benefits to themselves and to the potential recipient.' At many transplant centers both the recipient and the potential donors are informed that results of the donor's evaluation will only be revealed to the donor. In such a situation, the donor has an easy 'out' by claiming that the blood type or the cross-match did not allow for donation. Transplant centers should provide committed donors with every opportunity to change their mind up until the time of the surgery itself. When donors choose to opt out, the medical directors should provide the potential donor with the option of being declared 'inappropriate for medical reason' so that the

One year after the surgery, the donor was reported to have a herniated spinal disk, which was later denied to be related to the donation itself (Yoon, 1998; Confer et al, 2004). Thus it seems that after the harvest was done, the donor was not physically and psychologically protected at all.

Conclusion

Chasing bone marrow compatible for Sung-duk Bauman was documented in the media as a touching story, and the donor had to be volunteered to donate his bone marrow under intense social pressure. Unlike other transplantation stories, the stories focused on the recipient who became a hero who endured his unfavorable circumstances, not the donor to be altruistic to keep his brother. So, the right of the donor could be easily ignored. Former researchers studied compelled donation by children and incompetent adults (Cheyette, 2000; Confer *et al*, 2004; Goodwin, 2007; Goodwin 2009; Israni *et al*, 2004; Peters, 1991; Scheper-Hughes, 2007; Truog, 2005), but none paid attention to compelled donation by the individuals who are uniquely situated in a weak position such as mandatory army soldier or prisoner in custody. It can be argued that tissues and/or organ harvests from vulnerable persons or in a questionable situation should be strictly prohibited. The donations from vulnerable persons cannot easily fall into the category of altruism (Goodwin, 2007). This paper insists on free and voluntary donation of human tissue and/or organ, and not forced, commanded or mandated.

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relationship between potential donor and recipient is not adversely affected").

The Present State of Regulations Concerning Reproductive Medicine, Particularly Surrogacy, in both India and Thailand

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Abstract

If the Assisted Reproductive Technology (ART) (Regulation) Bill, 2013 (not yet officially disclosed, with the objectives of assisting infertile Indian couples and limiting commercial surrogacy), is passed as per the wishes of the Indian Ministry of Internal Affairs, then it is expected that the use of Indian surrogate mothers will be limited to infertile couples who are Indian nationals. As Thailand's law regulating reproductive medicine (surrogacy) was successfully enacted with the approval of the cabinet and King Bhumibol Adulyadej in July 2015, the developed world's reproductive medicine refugees will likely shift their attentions from India and Thailand to alternative countries, such as United States, Georgia, Cambodia and so on.

Keywords: Surrogacy, Medical Tourism, ART, Ethics, 2013 ART (Regulation) Bill

1. Introduction

By making medical tourism a national policy at the start of the 21st century, India and Thailand have become hubs for reproductive medicine (particularly surrogacy) within Asia, and achieved rapid economic development. However, since 2012, both countries have begun to experience major adverse changes in the support for foreign use of their reproductive medicine (surrogacy) services. This report provides updated information on this issue for the benefit of the researchers and patients of reproductive medicine.

2. India

2.1 Rapid changes in the state of reproductive medicine (surrogacy) in India

The Indian government, which authorized for-profit surrogacy in 2002, is now being challenged to alter the stance that it has maintained for over 10 years. As of May 2015, as a measure in response to numerous incidents involving surrogacy in recent years, the Indian government is hard at work preparing to enact the *Assisted Reproductive Technology (ART) (Regulation) Bill, 2013*. The bill, which follows the introduction of the obligation for foreign persons to obtain a medical visa when entering the country to use surrogacy facilities, tightens policies governing surrogacy and limits Indian surrogacy to infertile Indian couples.

What is the background to this strengthening of regulations?

2.2 Surrogacy incidents in India

Medical tourism is the national policy in India. In 2002, the government voiced its support for medical tourism, and in the same year the Supreme Court of India ruled that compensated surrogacy is lawful. Since then, India's surrogacy market has thrived year after year. However, beginning with the Manji Yamada incident[9] (July 2008), numerous serious ethical-legal issues[10] have arisen, forcing the Indian government to regulate for-profit reproductive medical tourism. With the Manji Yamada incident, India's Ministry of Health and Family Welfare (MHFW) hastily enacted the *ART (Regulation) Bill, 2008*, which is based on the *ART (Regulation) Bill, 2006*, and established the legal status of surrogate children. Furthermore, with the aim of properly ensuring the welfare of surrogate children, the Indian government revised the *ART (Regulation) Bill, 2008*, to enact the *ART (Regulation) Bill, 2010*.

Despite this, there has been no ebb in the flow of surrogacy hopefuls toward India, such as singles and same-sex couples, particularly from Australia.

2.3 Directives from the Indian Ministry of Home Affairs to the Ministry of External Affairs, July 9, 2012 and March 7, 2013

Concerned over the situation, the Indian Ministry of Home Affairs issued directives to the Ministry of External Affairs on July 9, 2012 and March 7, 2013. Following the announcement of the July 9, 2012 directive, the orders of the supervisory authority overseeing reproductive clinics were constantly violated. This was dangerous, and the lack of thorough measures to support ministerial orders regarding reproductive clinics prompted the subsequent toughening of surrogacy regulations by the Indian government. The Ministry of Home Affairs again sent a strict order on March 7, 2013 to the Ministry of External Affairs, demanding the thorough implementation of the intentions of the July 9, 2012 directive. With the announcement of this new directive strictly regulating surrogacy, foreign nationals visiting India for the purpose of commissioning surrogacy must now apply to the Foreign Regional Registration Office for a medical visa and exit visa.

The medical visa requires fulfillment of the following five conditions:

1. The couple is legally married and has been for at least two years, and consists of members of the opposite sex.
2. The applicants must provide a letter issued by the embassy of the home country in India or by the foreign ministry of the home country, stating clearly that (a) the home country permits surrogacy, and (b) the child to be born will be granted citizenship and permitted entry into the home country.
3. The applicants will take custody of the surrogate child.
4. The surrogacy treatment can only be carried out at one of the registered clinics recognized by the Indian Council of Medical Research (ICMR).
5. The surrogacy contract must be signed by the applicants and the prospective Indian surrogate mother, and notarized.

The exit visa requires fulfillment of the following two conditions:

1. Verified certificate clearly specifying that the applicants have taken due custody of the child.
2. Verified certificate clearly specifying that the Indian surrogate mother has relinguished custody of the child.

The result of the above directive is that clinics in India are now forced to refuse admission to foreign nationals wishing to commission surrogacy who do not hold a medical visa.

2.4 Can Japanese nationals wishing to commission surrogacy receive surrogacy treatment in India in the wake of these two directives?

As one of the conditions for issuing a medical visa, the Indian government requires *"a letter from the foreign ministry or embassy of the applicant's home country"* that authenticates that "surrogacy is permitted by the home country" and that "entry will be permitted and citizenship granted to the surrogate child by the home country." In Japan, given the lack of legislation related to surrogacy from which to make a decision, it is impossible for the Ministry of Foreign Affairs to issue such letters. At this point in time, Japanese nationals

[9] Manji Yamada was born to a Japanese obstetrician with the help of an Indian surrogate mother. However, as the couple who had commissioned the surrogacy divorced before Manji was born, by Japanese and Indian law, the female child (born of unmarried parents) was temporarily stateless. Afterwards, extra-legal measures were used to take Manji to Japan (Baby Manji Yamada Vs. Union of India & ANR. [2008] INSC 1656 (September 29, 2008)).

[10] Since the Manji Yamada case of 2008, as of December 2014, there have been 21 such incidents surrounding exit and entry. Since 7 cases among these involved homosexuals, and 4 cases among these involved singles, one can estimate that half of those commissioning Indian surrogate mothers are gay, lesbian, or single.

are unable to prepare the required documentation and therefore cannot apply for a medical visa from the Indian Embassy in Japan. As such, since 2013, India has ceased to be a host country for Japanese nationals wishing to commission surrogacy. Since 2013, the world's wandering 'reproductive medicine refugees'[11] have flocked to Thailand as a haven.

3. Thailand

3.1 Rapid changes in the state of reproductive medicine (surrogacy) in Thailand

In Thailand, since 2013, a rapid increase in surrogacy applicants has led to the occurrence of a number of reproductive medicine (surrogacy)-related incidents. In the backdrop of these problematic incidents, a major political change has taken place. After Yingluck Shinawatra, the 36th (and first female) Prime Minister of Thailand, was removed from office on May 7, 2014 over government corruption charges, the Commander in Chief of the Royal Thai Army, Prayuth Chan-ocha, declared martial law on May 20, and then launched a military coup and appointed himself the temporary head of state on May 22. With the acceptance by King Bhumibol Adulyadej on August 25, Chan-ocha became the 37th Prime Minister of Thailand. Accompanying the birth of this conservative government, Thailand, which had once been known far and wide as a haven for reproductive medicine (surrogacy) by patients from the developed world, underwent a drastic change in this industry. It was reported in 2013 that, for homosexual surrogacy hopefuls, "hundreds of agencies advertise their services online. While India used to be the hotspot – now it's Thailand."[12] However, as the government had been distressed by this state of affairs, it began a crackdown on surrogacy businesses immediately after inauguration, and the long-debated proposed ban on commercial surrogacy was approved by the temporary National Assembly in February 2015. Thus, as of 2015, Thailand is no longer a haven for gay surrogacy tourism. What triggered this crackdown?

3.2 Surrogacy incidents in Thailand

Of the numerous reproductive medicine (surrogacy)-related incidents that have occurred in Thailand, the two major incidents that have drawn the disfavor of the Chan-ocha military government are the August 2014 case of an Australian couple commissioning surrogacy who had returned home refusing to accept one of their twins with Down Syndrome, and the case of multiple surrogacies involving the young Japanese entrepreneur, Mitsutoki Shigeta, which had been uncovered soon thereafter.

In reality, before the 2014 multiple-surrogacy incident involving Shigeta, there had already been a foreigner surrogacy case in 2011 that had shocked Thai society. Babe-101, a Taiwanese surrogacy agency that had signed commercial surrogacy contracts with 15 Vietnamese women, was raided by Thai police on suspicion of human trafficking.[13]

After the May 22 declaration of the military coup, Prime Minister Chan-ocha, who had received reports from his subordinates of "the Thai homeland being a Mecca for both commercial surrogacy and sex preselection using preimplantation genetic diagnosis," ordered Thai police to conduct raids of 12 reproductive clinics in Bangkok on July 24. As a result, the Chan-ocha military administration, which views "paid egg donation, commercial surrogacy, and sex preselection using preimplantation genetic diagnosis" as "human trafficking,"[14] was promised by these clinics that they would no longer practice advanced reproductive medicine.[15]

Then, on July 31, the Chan-ocha administration met to officially decide on the "shut-down of Thailand's commercial surrogacy market." This was directly followed by the revelation of the multiple-surrogacy-baby incident at Shigeta's condominium. On August 5, 2014, Thai police stormed into the Bangkok

[11] The two major home countries of gay surrogacy tourists who have flocked to Thailand since 2013 are Australia and Israel. In Australia, neither surrogacy nor adoption for gay couples is recognized. For example, according to the Australian Department of Foreign Affairs and Trade documentation (More parents defy law with overseas surrogacy [*The Sydney Morning Herald*, September 14, 2013]), the number of Indian-born children applying for citizenship rose rapidly from 126 in the 2008 financial year (2007-2008) to 519 in the 2012 financial year (2011-2012) (among these, the number of Australians born in India averaged around 50 per year); similarly, Thai-born children applying for Australian citizenship jumped from 294 to 459. In the 2013 financial year, the number of Thai-born Australian citizenship applications increased even further. The proportion of gay and straight parents in these figures is estimated to be half and half. As a result, an increasing number of incidents, in which couples commissioning surrogacy encounter difficulty in bringing the surrogate child home, have occurred. In Thailand, this has usually been resolved through the following administrative procedure. The surrogate mother and the sperm donor are written down as mother and father on the surrogate child's birth certificate, and the surrogate mother then signs a release relinquishing parental rights. Finally, the surrogate child obtains citizenship based on a DNA test with the commissioning father. However, with the passing of the 2015 bill banning surrogacy, all forms of surrogacy for foreign nationals was banned, whether they are for business or non-profit treatment purposes.

[12] Wombs for hire: Aussie couples flock to Thailand to find surrogates [*SBS The Feed*, Oct 29, 2013].

[13] Surrogate moms to give birth in Thailand [*Thanh Nien*, 3/11/2011].

[14] Thai generals had surrogacy in their sights [*Sydney Morning Herald*, August 9, 2014].
Chan-ocha is not alone; Director Saowanee Khomepatr of the Ministry of Social Development and Human Security also shares his view, stating: "The government and the Prevention of Human Trafficking Act view commercial surrogacy as a form of human trafficking." (Wombs for hire: Aussie couples flock to Thailand to find surrogates [*SBS The Feed*, Oct 29, 2013]).

[15] Sex-selection reports trigger investigation of fertility clinics [*THE NATION*, March 25, 2014].

condominium of the 24-year-old Japanese man, Mitsutoki Shigeta, and seized nine infants. The raid by Thai police was prompted by reports by neighbors in the condominium complex, who were concerned about the sound of many crying babies. However, long before these reports, Dr. Mariam Kukunashvili, the director of the Thailand-based reproductive medicine intermediary organization, the New Life Global Network[16] (whose headquarters is in Georgia), had submitted reports to the International Criminal Police Organization (ICPO) and the Japanese Embassy in Thailand. Dr. Kukunashvili had suspected human trafficking when she personally received a new application from Shigeta for regular surrogacy (10-15 children per year[17]) after the New Life Global Network had already introduced him to two Thai surrogate mothers, and thus strong suspicions had been held regarding Shigeta a year before the Thai police acted. The condominium searched by the Thai police was already registered as the residential address for 21 infants (12 males and 9 females) born from eggs provided by women from various countries within Europe and Asia. Whether or not Shigeta had intended to distribute his assets to his children in Thailand, where inheritance tax is not required, and pass on his business[18] (based on statements by the Thai doctor who had dealt with the surrogacy requests of Shigeta and the Thai lawyer of the agency involved), the previously unheard-of plans to create masses of children by a 24-year-old Japanese man are not only inconsistent with accepted morals in Japanese society, but also greatly divergent from general international moral standards. Moreover, he has also been accused of contravening the United Nations Convention on the Rights of the Child, to which both Japan and Thailand are signatories.

While investigations continue into this case, the motivations for which remain unclear, Thailand's largest surrogacy service, the All IVF[19] Clinic (owned by Dr. Pisit), was revealed as one of those contracted by Shigeta, after it was searched on July 24. The Chan-ocha military administration ordered a second search on August 8, which led to the forced closure of the offices of the clinic[20] on grounds that the business in one of them was unauthorized and unregistered.[21]

3.3 Passing of Thailand's first law regulating reproductive medicine (surrogacy)

The occurrence of reproductive medicine (surrogacy)-related incidents in such rapid succession triggered the Chan-ocha military administration to label "paid egg donation, commercial surrogacy, and sex preselection using preimplantation genetic diagnosis" as "human trafficking," and the temporary National Assembly passed the *Bill to Protect Children Born Through Assisted Reproductive Technologies, 2015*, which is the first of its kind, when it met on February 19, 2015.

When passing the surrogacy ban of February 19, 2015, the Chan-ocha administration considered two major issues – the prohibition of commercial surrogacy and the regulation of altruistic surrogacy – and based the ban on the abandoned *Bill to Protect Children Born Through Assisted Reproductive Technologies, 2010*.

3.4 Can Japanese nationals wishing to commission surrogacy receive surrogacy treatment in Thailand in the wake of the establishment of this regulatory legislation?

The bill was approved by the cabinet and King Bhumibol Adulyadej and came into effect in August 2015. As well as banning for-profit surrogacy, the bill limits commission of non-profit surrogacy to "legally married couples of Thai nationality" and "couples legally married for a period of at least 3 years, one party of which holds Thai nationality." It also limits the surrogate mother to "a blood relative of at least 25 years of age who has already given birth." This language completely eliminates the opportunity for foreign couples, including the Japanese, to receive surrogacy treatment in Thailand.

4. Conclusion

If the *ART (Regulation) Bill, 2013* (not yet officially disclosed, with the objectives of assisting infertile Indian couples and limiting commercial surrogacy), is passed as per the wishes of the Indian Ministry of Internal Affairs, then it is expected that the use of Indian surrogate mothers will be limited to infertile couples who are Indian nationals.[22]

[16] This reproductive medicine agency, headquartered in Georgia, also has offices in India, South Africa, Poland, Armenia, and the Ukraine, and is a commercial organization dealing with egg provision and surrogacy services (The brave new world of the international egg trade [*Mail & Guardian*, May 17, 2013]).

[17] *Jiji Press*, August 14, 2014.

[18] Asahi Shimbun Digital, August 8, 2014 / Global News Asia, August 11, 2014. As of 2014, foreign nationals are limited to the purchasing of condominiums. However, looking towards the Association of Southeast Asian Nations (ASEAN) Integration 2015, Thailand is making moves to deregulate investments into Thai real estate, the prices of which continue to rise. If Thailand's real estate market is deregulated, expatriates who have gained Thai citizenship will also be able to buy Thai land. In other words, the agency's lawyer likely meant that Shigeta had planned to buy property in Thailand, where there is no inheritance tax, under the names of his children (the surrogate children) after distributing his assets to them. Rather than appear before the Thai police, Shigeta has submitted via his lawyer documents proving the reason for commissioning the surrogacies and his financial competency for raising the children. As of January 2015, he is in the process of filing a civil suit against the Nonthaburi Province in the suburbs of Bangkok for the return of the surrogate children, who are currently in government care.

[19] In Vitro Fertilization

[20] Sivatel Bangkok hotel 12F&15F.

[21] [*Bangkok Post*, 8/8/2014] The All IVF Clinic, shut down on August 8, had 165 surrogate mothers.

[22] However, there is inconsistency in the stances of India's Ministry of Home Affairs and Ministry of Health and Family

As Thailand's law regulating reproductive medicine (surrogacy) was enacted from August 2015, the developed world's reproductive medicine refugees will likely shift their attentions from India and Thailand to alternative countries, such as Mexico and the United States.

Issues of Research Ethics in Developing World

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Introduction

In this world of today, one can easily see the dramatic inequalities among developing and developed countries. From the availability of safe water supply to health care i.e. from social needs to health care needs, there is a great demarcation and discrimination amongst these both. Particularly, health care is demarcated significantly in these regions because in developed countries disease burden is equivalent to allocation, availability and access to health care resources. However, the situation of developing countries is opposite i.e. there is increased disease burden and decreased health care resources. These inequalities have resulted in more disease burden and shorter lives in developing countries. As a result of these inequalities and absence of the essential safeguards and protection of human rights, the research in health care in developing countries is also in debate. The status quo of research in developing countries is such that some research that is being done in developing countries are purely altruistic whereas, others are driven for economic or academic interest. It is important here to state that there is intense need for research in developing countries because of the disease burden and the 10/90 gap in research between developing and developed countries (WHO). In this paper an attempt will be made to highlight some of the ethical issues related to research in developing countries and an effort will be made to provide recommendations for ethical clinical research in developing countries especially in Pakistan.

The ethical framework that is being followed is basically based on the four principles approach, i.e. duty to alleviate suffering, duty to show respect for persons, duty to be sensitive to cultural differences and duty not to exploit the vulnerable. In addition to this, it is important to take local social, cultural and economic contexts into account. If this framework is being kept in mind then the key ethical issues those are very evident while conducting research in developing countries are: the vulnerable population, the issue of genuine consent, the debate standard of care, socio-cultural as well as economic factors, assessment of risks and benefits, post research benefits, issue of privacy and confidentiality.

Developing Countries Population as Vulnerable

It is important to realize while conducting research in developing countries that the population or the group of people whom researchers are inducting in research studies are vulnerable for various reasons. The research population of developing countries is a vulnerable group because they are economically and educationally disadvantaged. The population in developing countries is striving for their basic necessities i.e. food, shelter and water. More than half of the population is living below poverty line and does not have access to basic necessities of living, for example, safe water. This group of people does not has access to basic resources related to health care and most of the population residing in developing countries is illiterate, they are unaware about their rights therefore they are unable to take a strong position. All these factors make this population vulnerable, and in this situation the responsibility of researcher while doing research that involves such population seems difficult and a challenging task. It becomes increasingly important to take careful measures in order to prevent developing country population from exploitation that could be result of induction in research study. The recruitment process should therefore be of special consideration for researcher to maintain integrity of vulnerable population and to prevent exploitation.

Genuine Informed Consent

According to Beauchamp and Childress, the concept of informed consent revolves around five basic domains i.e. competence and capacity, disclosure, understanding, voluntariness and consent or refusal. Overall the population in most developing countries is educationally disadvantaged, the level of education of the people living in developing country covers a wide range and most of the population is illiterate. In addition, varieties of local languages are spoken in different parts of the country, especially referring to Pakistan. Though these individuals are competent and have capacity to make rational decisions for them

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Welfare (MHFW) regarding the granting of permission for surrogacy commissioning by singles. In 2013, a Sudanese surrogacy hopeful raised a statement of protest at the High Court of Punjab and Haryana against the Ministry of Home Affairs directive "to limit Indian surrogacy to infertile Indian couples." While the Ministry of Home Affairs responded by submitting the July 9, 2012 and March 7, 2013 directives (which called for strict regulation) to the High Court, the Indian Council of Medical Research (ICMR), which is run by the MHFW, submitted the *ART (Regulation) Bill, 2013*, which recognizes the commissioning of surrogacy by singles. Ministries differ on single surrogacy [*The Times of India*, Nov 2, 2013].

however, above mentioned factors present inordinate challenges to researchers in the process of obtaining informed consent as comprehension and understanding of informed consent is extremely indeterminate in the existence of the element of language barrier. Furthermore, coercion in any form makes informed consent invalid and referring to developing country research participant's conditions, it becomes vital to exclude the component of therapeutic misconception and ensure that participation is absolutely voluntary. However, it is recommended that individual genuine consent should be obtained from the research participant so that their autonomy is being respected but in some cultures that are prevalent in developing countries it may also be appropriate to obtain agreement of a community leader or head of the family but it should be kept in consideration that taking consent from community leader or head of the family doesn't eliminate the requirement of taking consent from individual who is actually research participant and individual consent should be a primary goal in each research. It is important to take appropriate measures to obtain genuine informed consent so that the individual's autonomy is not being violated by any means and valid attempts should be made for this purpose in order to ensure that their decision to participate in research study is truly autonomous.

Standard of Care

It is a significant subject to discuss standard of care here because of the international debate about standard of care is about the question of what should be the standard of care while doing research in developing countries? Should it be local or global? If local then, would provision of locally available best current treatment is considered as violation of the principle of justice? Many of the international guidelines have also addressed this issue but are unclear and insufficient to answer question completely; for example, CIOMS guide line 11 clearly states that a control arm should receive the established effective intervention but it doesn't say local or global because both could be different especially if we are referring to developing countries versus developed ones, paragraph 29 of the Declaration of Helsinki states that: "*The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods."*

The concept of distributive justice places all individuals at an equal place regardless of any confounding factors and if developing countries are treated differently by researcher then the principle of distributive justice is being violated. A few of the important questions related to research ethics standard of care debate are: is it ethical to lower down ethical standards just for the purpose of generating well proven scientific knowledge? Are we considering humans living in developing countries and participating in research as merely means to generate scientific knowledge? Then the concept of human dignity is lost.

Socio-cultural and Economic Factors

The socio-cultural factors mainly concerned with research in developing countries refer to the social value of the research that must be determined during the initial phase of research study and subsequently, should also be deliberated to the population. The area of concern here is that most of the time it is the researcher that defines the research subject according to his need and select the locality from his level of understanding so the research area that the researcher is interested into can be different from the need of that locality. In this way the question is how one can determine the social value of the research if somebody else is taking decisions on their behalf that is not the part of that culture and society? However, the economic factors mainly include the problem of inducement that can direct the participant's decision to participate as their economic condition is also not up to the mark. This can make the decision of participation to be the result of coercion, which is unethical.

Power Dynamics

The issue of power dynamics i.e. the relationship amongst the research subjects and research community, and research subject and researcher is a very apparent concern in the area of research ethics in developing countries. As discussed earlier that the population of developing country is educationally disadvantaged therefore it is often believed that the purpose of research whether observational or placebo controlled trial is to provide benefit to study participants and if anyone denies participation in research they will be harming themselves, as they will not be getting benefits out of research intervention or study. The element of therapeutic misconception in either way may also there because most of the time the participant's perception is that they are getting benefit out of research as it is being conducted here for their good and intervention is beneficial for them. The second staged power dynamics is also present, if the community leader or elder family member has provided the consent then it is difficult for an individual so say no against it. Their decision not to participate may sometimes also lead to rejection by the community or tribe in which they are living. Beside this, another emerging issue is of privacy and confidentiality of the communities where the research is being conducted in developing countries. It is important to maintain privacy and confidentiality of these communities so that they can be prevented from stigmatization.

Post Research Benefits

The concept of post-research trial responsibilities raises many questions especially the questions that are related to ethics. The first important thought is that is it ethically acceptable to conduct a research in a country that in future may not be able to afford to provide the treatment that is effective? The second thing is that if the trial is successful and the intervention is beneficial then should that intervention be provided after the trial is over? And if we say yes, then the question arises of

who should be responsible for making that effective intervention available? Is this the responsibility of the researcher, institution or the sponsor?

In order to have a broader perspective, let us view the issue of post-research trial responsibilities in the light of international guidelines, so that it can be determined that what does guidelines says about research enterprise post-research responsibilities. It will not be wrong to say that up till now it has been accepted that the ethical responsibilities of researcher as well as of sponsor, towards the participants of trial do not come to an end on the completion of research trial. In other words, determination and provision of post-research trial benefits is becoming an integral component of research. Many guidelines are developed that address these guidelines include WHO, Helsinki and CIOMS. According to WHO guidelines *"investigators have a responsibility to trial subjects once the trial is over"* (WHO, 1995) but this guideline is just pointing out the issue and is not defining it in detail. Referring to the guidelines developed by World Medical Association's declaration of Helsinki regarding post-research trial responsibilities, it states that *"at the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study"*, but this does not specify what assured of access means when it comes in practical terms, or who has the responsibility to assure it? According to CIOMS guideline that is referring to post-research trial benefits and responsibilities, *"before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that … any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community".* In this guideline, although the direction towards placing the responsibility is shown i.e. on sponsor and investigator, however, the term reasonable availability is vague and open to interpretation. Thus, by reviewing these guidelines it can be concluded that although it has been identified that there is essential to provide post-research trial benefits but this thing is still in doubt that who's responsibility it is? From whom should and are we expecting to provide post-research trial benefits? What are the responsibility of research enterprise, e.g. researcher, institution and sponsor with respect to post-research trial benefits provision especially in developing countries. This is a complex issue because to answer these questions is abstract because beside these questions there are other areas of concern as well for example, what should be provided to the control group, all participants and to the community once research is over? These types of decisions should be made and negotiated before the study has actually begun. This problem can only be overcome if the gate keepers of the community start negotiating prior to the study having been initiated in that area so that their needs are also being fulfilled and that community is not being used as merely means to conduct research. There is an intense need that developing countries should set their own priorities for research into health care.

Role of Ethical Review Committees (ERCs)

ERCs can play a vital role with regard to research conducted in developing countries because effective ethical review of research provides crucial safeguards and determines scientific validity as well as ethical acceptability. The condition of developing countries ERC is likely to be vulnerable because of their level of independent working, competency, quality ethical review, conflict of interest and minimal monitoring. There is an intense need to build expertise because the expertise to undertake research at local level is severely limited, there is not enough training and these are too limited for local researchers. Genuine attempts should be made to strengthen expertise in research and to develop institutions. Maximum opportunities should be provided for transfer of skills and knowledge. Besides building of expertise, capacity building should also be the focus of developing countries' ERCs and moreover, an infrastructure should be developed that must have officially recognized regulations and guidelines. However, there are also related challenges. These challenges includes which guideline to use? Who should monitor research, and how? How can we ensure that adequate ethical review is being done for a research proposal? And most importantly, what sort of ethics training is appropriate and adequate? Along with these challenges developing countries also lack laws and regulations governing ethics in research and international guidelines are increasing in number but these are not harmonized and are conflicting to each other. In developing countries, such as Pakistan ERC should be established but with the following considerations i.e. it should have members with expertise in scientific and methodological aspects of research that is under review, it should clearly indicate the regulations or ethical guidelines they use, it must have rules of procedure, record keeping and should be accountable. By doing this, the research that is being done in developing countries could be made more ethical. It should also be kept under consideration that any international research and externally sponsored research must go through local ERC approval so that the developing countries population can be protected from the issues discussed above extensively.

Conclusions

To conclude this discussion, we have to realize that the developing countries are vulnerable and if research is being done on communities residing in developing countries then special consideration and attention should be given so that they can be protected from further exploitation. The following considerations should be kept under contemplation. These countries should set national priorities that are related to provision of health care so that their capacity can be enhanced to conduct relevant research according to their needs. Research relevance should be justified to appropriate ERCs especially when the research is

externally sponsored. Measures should be taken to build and strengthen effective ethical review of research that should be independent of government and sponsors. Sponsors of national and international research should ensure that adequate provision is made for training in ethics of research for professionals involved in research related to health care. And finally, development of local expertise in provision of health care research should be an integral component of any proposed research.

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Responsible Innovation and Ethics: A need for Globalization

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Abstract

Background: Innovations ranging from science and technology to the social continue to shape human development. Innovations appearing in one geographical area influence other geographical areas, in a shorter timespan than ever before. How to regulate innovation processes and products has been discussed for some time. Ethics theories and reasoning are used to give members of society guidance on how to act and relate to each other. Responsible innovation (RI) is a framework initially proposed to integrate social and ethical considerations with the practice of innovation.

Objective: To investigate a) how ethics is covered within the RI literature covered; b) the geography of the authors contributing to the RI academic literature and c) within which geographical context RI and innovation is discussed.

Methods: To obtain quantitative and qualitative data we searched four academic databases (EBSCO All – an umbrella database that consists of over 70 other databases, Scopus, Science Direct and Web of Science) for the phrase "responsible innovation" either in the article title, article abstract, article keyword, under "topic" in the case of Web of Science, or in the title of the journal. We furthermore searched for the phrase "responsible innovation" on the European Commission's web site. All together 326 relevant articles were downloaded for content analysis

Results: We found a geographical imbalance of a) authorship, b) coverage of innovations, c) engagement with RI and d) ethics reasoning and ethics theories employed.

Conclusion: The RI discourse in general and the ethics coverage within the RI discourse needs to be globalized in order for it to reach its full potential.

1. Introduction

Innovations ranging from science and technology (S&T) to the social change continue to shape human development. Innovations appearing in one geographical area influence other geographical areas, in a shorter timespan than ever before [1-11]. For example Chinese innovations such as cast iron, chain suspension bridge, wheel barrow, silk textile, gunpowder, porcelain, paper, printing, compass and sailboat are part of the daily life of most humans globally [12]. Innovation agendas differ between geographical areas and countries as do the ways how innovation procedures are embedded within a country or geographical area [13-20]. As a political agenda, government bodies of countries in the Global North [e.g. 21,22,23] and Global South [24-29], have developed strategies and infrastructures around S&T with the aim to benefit their countries. For example the Organization of American States (OAS), composed of 35 independent states of the Americas, has identified S&T as 'the primary driving forces of today's global economy' [30]. The OAS regards S&T as an integral development for the Americas in generating employment and well-being through innovation and the commercialization of new products and services, reducing poverty, improve education, health, nutrition, and trade; and building new capacities required in the 21st century' [31]. Member states of the Association of South East Asian Nations (ASEAN) (Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Viet Nam), reflecting on the influence of S&T on member states, perceive S&T as "a key factor in sustaining

economic growth, enhancing community well-being and promoting integration in ASEAN" [32].

1.1 Responsible Innovation

How to regulate innovation processes and products has been discussed for some time [33-39]. In recent times the European Commission has focused on developing a framework for innovation that incorporates the consideration of the societal impact of innovations in the design process [40]. As part of the policy movement toward Responsible Research and Innovation (RRI) in Europe, the European Commission identified six key dimensions in the "Science in Society" initiative framework under the Horizon 2020 programme [41]. RRI consists of designing and implementing R&I policy that will a) engage society more broadly in its research and innovation activities, b) increase the access to scientific results, c) ensure gender equality in both the research process and research content, d) take account of the ethics dimension, and e) promote formal and informal science education all of which are under the umbrella of the sixth dimension of governance [42,43]. As the concept of RI continued to develop and evolve within the academic literature, the EC added the dimensions of "sustainability" and "social justice/inclusion" to RI [44]. The framework of responsible innovation (RI), as proposed by the UK Research Council, is based on four dimensions: anticipation, reflexivity, inclusion, and responsiveness [45]. RI is seen as a *"a transparent, interactive process by which societal actors and innovators become mutually responsive with regard to the (ethical) acceptability, sustainability and societal desirability of an innovation and its marketable products"* [46]. It is seen to take "care of the future through collective stewardship of science and innovation in the present" [45]. Finally, *"[Responsible innovation is a] broader reconfiguration, one that creates opportunity for innovation toward socially desirable ends, as well as opportunities for timely management, is needed. A reconfiguration that is values- and not rules-based, that is flexible in the face of uncertainty, and that allows us to take collective responsibility for a future which science and innovation play such critical roles in shaping"* [47].

1.2. Global regulation

Ethics theories and reasoning are used to give members of society guidance on how to act and relate to each other [48]. Ethical reasoning is a global endeavor [49-59,48,60-66]. UNESCO (United Nations Educational, Scientific, and Cultural Organization), a UN agency responsible for science and technology, culture and education is since the 1970's involved in the ethics of science and technology [67] and has a bioethics capacity-building programme, the Intergovernmental Bioethics Committee and International Bioethics Committee.

A resolution adopted by the General Assembly on 27 July 2012 called *The future we want* stated under point 275: *"We recognize the importance of strengthening international, regional and national capacities in research and technology assessment, especially in view of the rapid development and possible deployment of new technologies that may also have unintended negative impacts, in particular on biodiversity and health, or other unforeseen consequences"* [68]. The outcome document of the Third International Conference on Financing for Development: Addis Ababa Action Agenda that took place in 2015 states under point 5: *"We recognize that appropriate incentives, strengthening national and international policy environments and regulatory frameworks and their coherence, harnessing the potential of science, technology and innovation, closing technology gaps and scaling up capacity-building at all levels are essential for the shift towards sustainable development and poverty eradication"* [69]. Under point 9 the document states: *"9 Processes to develop and facilitate the availability of appropriate knowledge and technologies globally, as well as capacity - building, are also critical"* [69]. Under point 123 the document mentions the establishment of a technology facilitation mechanism in order to support the sustainable development goals and which will be *"based on a multi-stakeholder collaboration between Member States, civil society, the private sector, the scientific community, United Nations entities and other stakeholders and will be composed of a United Nations inter-agency task team on science, technology and innovation for the sustainable development goals, a collaborative multi-stakeholder forum on science, technology and innovation for the sustainable development goals and an online platform"* [69]. The document outlines that *"the online platform will be used to establish a comprehensive mapping of, and serve as a gateway for, information on existing science, technology and innovation initiatives, mechanisms and programmes, within and beyond the United Nations. The online platform will facilitate access to information, knowledge and experience, as well as best practices and lessons learned, on science, technology and innovation facilitation initiatives and policies. The online platform will also facilitate the dissemination of relevant open access scientific publications generated worldwide"* [69].

The purpose of our study was threefold; to investigate a) how and to what extent the RI academic literature engaged with ethics principles, theories, approaches, and reasoning; b) the geography of the authors contributing to the RI academic literature and c) within which geographical context RI and innovation is discussed in the RI literature.

2. Methods

2.1 Data sources

To obtain quantitative and qualitative data we searched four academic databases (EBSCO All – an umbrella database that consists of over 70 other databases, Scopus, Science Direct and Web of Science) for the phrase "responsible innovation" either in the article title, article abstract, article keyword, under

"topic" in the case of Web of Science, or in the title of the journal. N=185 articles were downloaded for use. In addition, we downloaded all articles (n=61) published in the Journal of Responsible Innovation by Taylor Francis since its beginning in 2014 till the month of April 2015. We chose this journal as it is the first journal focusing solely on RI. This journal did not show up in the four databases we covered. We furthermore searched for the phrase "responsible innovation" on the European Commission's web site (at http://ec.europa.eu/index_en.htm) as the European Commission is very visible in the discourse of RI and n=80 documents were downloaded, which included press releases and speeches in addition to policy documents.

2.2 Data collection and analysis

N=246 articles from the academic sources were sorted into two general categories, those articles published in the Journal for Responsible Innovation ("JRI") and those published elsewhere ("Non-JRI"). The articles taken from the Journal of Responsible Innovation were published in January of 2014 or later. The articles in the "Non-JRI" category had publishing dates ranging from 1979 to 2015. These were coded alongside the n=80 documents downloaded from the EC website ("EC Documents").

All downloaded documents were imported into atlas.ti 7™ software for both quantitative and qualitative analysis. We used the auto-coding function of atlas.ti 7™ software to determine hit counts of keywords of interest such as ethical principles and approaches and to flag areas that covered RI. The articles were read to gain qualitative data related to a) coverage of RI, b) how ethics was used, c) which countries and regions were covered in which way within the context of RI and Innovation and d) the geographical origin of the authors of the articles.

2.3 Limitations

We only searched four academic databases and as such our findings cannot be generalized to the whole academic literature. We only analysed English language articles and as such our conclusions cannot be extended to non-English language literature. However, we posit that our data can be used to guide future research in this area. The EC documents were limited to those that were available in the .pdf file format, and to those documents that were available online through the EC website in English.

3. Results

3.1 Ethics

As to the first research question of how ethical principles theories, concepts and approaches are covered within the RI literature we found the following (Tables 1 and 2).

Table 1 reveals that many ethics terms and the term ethic itself have been used frequently in the literature covered. It is in particular striking that 93.4% of the articles in the Journal for responsible innovation contained the term "ethic". If we look at the four bioethics principle influential for example in North America [70], two of the principles are used substantially, namely autonomy is covered in 26.2-40% of the articles covered and justice is covered in 14.1-36.1% of the articles. Harm as a concept is also covered in 32.8-71.2% of the articles covered. Finally care as a concept was mentioned in 56.2-78.8% of the articles covered.

Table 1: Hit counts for and percentage of articles that mention ethical principles and keywords

Term	JRI (n = 61 articles = 100%)	Non-JRI (n = 185 articles = 100%)	EC Documents (n = 80 articles = 100%)
	Count (%)	Count (%)	Count (%)
Ethic	93.4	44.9	63.8
Value	86.9	89.2	81.3
Care	59	56.2	78.8
Moral	55.7	26.5	18.8
Justice	36.1	14.1	22.5
Harm	32.8	50.3	71.2
Autonomy / autonomous	26.2	23.8	40
Societal value	9.8	8.1	5
Virtue	9.8	10.3	2.5
Utility	9.8	41.6	15
Beneficence	0	1.1	0
Maleficence	0	0	1.3

Table 2: Hit counts for and percentage of articles that mention ethical approaches by data source

Term	JRI (n = 61 articles = 100%)	Non-JRI (n = 185 articles = 100%)	EC Documents (n = 80 articles = 100%)
	Count (%)	Count (%)	Count (%)
Precautionary Principle	9.2	11.5	16.3
Institutionalism	6.6	5.9	3.8
Consequentialism	4.9	3.8	0
Feminism I feminist	3.3	2.2	1.3
Utilitarianism	3.3	2.7	0
Constructivism	3.3	5.9	0
Virtue Ethics / Virtue Theory	1.6	3.2	0
Deontological theory	1.6	3.2	0
Egoism	1.6	1.6	0
Libertarianism	1.6	0	0
Relativism	0	1.6	1.3

Table 2 reveals that specific ethics theories and approaches are much less engaged than general ethics concepts. Despite the use of ethical theories to build ones' case through ethical reasoning, they are rarely mentioned explicitly in the literature we explored. We

found within the 4331 quotations generated for the code "ethic*" from our 246 articles that some debate the use of a certain ethical theory as a basis for RI over another [45,71-77]. Some papers discuss the consequences of adhering to specific ethical theories when developing the framework of RI, and critique the current approaches [78,72,75]. Most hits however only reveal a reiteration of the importance of ethical considerations in the practice of RI [45,72-77] without engaging with it conceptually.

Table 3: Origin of authors

Code	JRI (n = articles of authors from a given country)	Non-JRI (n = articles of authors from a given country)
Europe		
Austria	0	3
Belgium	2	2
Denmark	1	2
Finland	0	8
France	1	17
Germany	3	23
Greece	0	2
Italy	1	26
Lithuania	0	1
Norway	1	5
Portugal	0	1
Poland	0	1
Romania	0	1
Slovenia	0	1
Spain	0	8
Sweden	0	2
Switzerland	0	4
The Netherlands	12	25
Turkey	0	4
UK	9	18
North America		
Canada	4	6
USA	29	18
Asia		
China	0	4
India	0	1
Japan	0	6
Korea	0	3
Malaysia	0	2
Thailand	0	1
Taiwan	0	1
Other		
Argentina	0	1
Australia	1	2
Brazil	1	2
Israel	0	4
Mexico	0	1
Pakistan	0	1
South Africa	0	2
Syria	0	1

Furthermore Table 2 reveals that many ethics theories and approaches in existence are not applied yet or seen as useful or a threat to RI in the RI literature. One reason why certain ethics approaches and theories are not mentioned might be due to the geographical origin of authors and geographies covered.

3.2 Geographical coverage

As to the question of the geographical coverage of RI we investigated a) from where authors of the RI articles originate from (Table 3) and b) which geographical regions were mentioned in the articles (Table 4).

Table 3 reveals that most authorships originate from a few European countries and the USA with very few from Asia and South America and many other countries missing. This may also represent the general academic literature.

Table 4 reveals that Europe and the US are mentioned in over 60% of the articles in the JRI and non-JRI articles whereby Asia is mentioned much less. Canada is also covered much less.

Table 4: Geographical regions mentioned in the JRI and non-JRI articles

Code	JRI (n = 61 articles = 100%)	Non-JRI (n = 185 articles = 100%)
America* / United States / US	86.9	91.4
Europe*	63.9	75.1
Canada	14.8	15.7
Asia	9.8	18.9
Near East	1.6	4.9
Middle America	0	0
South America	0	2.1

Reading the articles to obtain data on which countries where specifically linked to RI we found that the countries covered were mostly from Europe and North America. One article [79] covered a workshop between UK and Brazilian scientists looking at RI suggesting that the RI discourse is linked too closely to European and North American thinking and realities. Many countries that have shaped innovation processes and generate innovative products in recent times such as China and South Korea have not been mentioned in relation to RI although articles mentioned that China and South Korea are innovators. One 2008 article covered RI of nanotechnology in Japan covering societal impacts of nanotechnology from 2004 which was the launch of the Nanotechnology and Society open forum till 2007 with the ''Nanotechnology Debate'' discussion forum and outlines the policy recommendations from a project called Research on Facilitation of Public Acceptance of Nanotechnology [80]. India was mentioned in regards to personalized medicine in the age of pharmacoproteomics [81] and agribiotechnology and agrinanotechnology [82]. Pandey outlined the problem he sees in the existing RI discourse. He states that power dynamics are a

neglected aspect in the "overall debates on responsible innovation". Pandey argues that the RI discourse is based on the "interplay of the relationship between two broader categories" namely a) The creation of an innovation environment, and b) the Governance of the innovation environment. Pandey proposes a 'beam-balance' metaphor to engage with the idea of 'Responsible Innovation' in order to take the inequalities and alternative perspectives into account" [82]. Pandey argues further *"that the criteria of technological choice which rely only on cost and returns, commercial viability, export potential and contribution to GDP are insufficient. The socio-technical imaginary needs to be envisioned on a premise of sensitivity to broader understandings of risks, uncertainty, ethics and social structure and accommodative of alternatives"* [82]. Pandey cites [83] when he states that *"Responsible innovation thus needs to be constantly self-reflexive by having greater awareness of the histories, cultures, and normative frameworks that have led and regularly lead to the ethical conundrums of an 'irresponsible' innovation"* [82]. However Pandey did not employ ethics theories as such to make his case.

4. Discussion

We found a geographical imbalance of authorship in the RI literature we explored geographical imbalance of context within which RI and innovation is discussed and an uneven use of ethics theories, concepts and approaches. The articles that discuss ethical principles in the Non-JRI category discuss mostly business ethics and financial responsibility in the sense of what types of behaviour and guidelines constitute responsible business practice. Most of the discussion in the RI literature is around consequentialism, deontological ethics and virtue ethics approaches [78,72,75,74,84,85]. Some articles weigh the pros and cons of the adherence of one ethical principle over another in the practice of RI [78,72,75,47]. An article [79] asks whether a feminist concepts of care that they see to frame Northern conceptions of RI translate into non-Western and Global South context. If the geographical authorship of the English language RI literature including the literature covering business ethics would be more diverse it is reasonable to expect that more ethical principles and ethics theories would be covered and the pros and cons of a given approach would be discussed more. This is of particular importance given the global impact of innovation processes and products.

An article by [79] states: *"It was also recognized that although RI has developed in the context of, and as a policy response to, controversial or questionable forms of technological innovation, an enormous variety of social innovation occurs in the global South, directed specifically at social and/or environmental goals and sometimes as a means of adjustment-response to inadequately designed or badly chosen technological innovations. RI needs to consider its role, if any, in accommodating and encouraging such innovation too, generating recommendations for a more socially focused, and less high-tech focused, innovation policy."* Indeed if we look at the group of disabled people (people labeled as impaired) it is well reported that the focus on high tech solutions is often a problematic one especially for the Global South [86]. It is thematized by many as a problem that technological solutions are put forward often to rectify social problems [87-93]. A more diverse authorship might have thematized that issue more.

The need for a more geographically diverse coverage of RI in general and the ethics reasoning in particular is also evident if we look at the 2015 outcome document of the Third International Conference on Financing for Development: Addis Ababa Action Agenda [69]. This document gives voice to the opinion that a harmonization of national and international policy environments and regulatory frameworks is needed in order to harness *"the potential of science, technology and innovation, closing technology gaps and scaling up capacity-building at all levels" which are seen as "essential for the shift towards sustainable development and poverty eradication"* [69]. The outcome document states that *"processes to develop and facilitate the availability of appropriate knowledge and technologies globally, as well as capacity - building, are also critical"* [69]. The RI discourse could play an important role if it finds a way to be more global in its scope of contributions. The question is how the RI literature adds to the capacity to evaluate technologies and to generate appropriate knowledge? Some academic literature on RI thus far has been focused on the methods through which the ties between society and innovators can be forged in the practice of RI [94-96,77,97,98]. However, the coverage is culturally too homogenous and therefore missing certain problems or opportunities that could exist in linking society with innovators and how to regulate innovation.

The outcome document [69] proposes the development of an online platform to facilitate *"access to information, knowledge and experience, as well as best practices and lessons learned, on science, technology and innovation facilitation initiatives and policies"* and *"to facilitate the dissemination of relevant open access scientific publications generated worldwide"* [69]. Furthermore, open access is one dimension of RI outlined by the European Commission (EC) documents (see for example [42,43]). We posit that the open access is a challenge for the RI academic discourse. Nearly every one of our 246 articles was not from open access sources. If open access is to become a reality and if technology governance scholars and other stakeholders want to make use of the global open access online platform outlined by the Addis Ababa Action Agenda [69] to have their academic work made available to multi-stakeholder groups worldwide, the scholar might indeed have to think hard where to publish. What open access options do exist? What is the cost of publishing open access? We posit open access might be beneficial for a more geographical diverse engagement with what RI is and should be

globally. However the cost factor has to be dealt with given that many journals charge author fees to make ones article open access. Or is one to give not the latest version of a published document to the online platform [69], one that one is also allowed to put into ones University online repository?

5. Conclusion

In conclusion, there is a marked geographical imbalance of authorship and countries/regions engaged with in the content of the English language RI literature. Additionally, although ethics as a concept has been engaged with substantially in the RI literature we explored, our findings suggest that certain ethical concepts, views and reasoning are not present which could be due to the geographical imbalance of authorship a regions engaged with. Our findings indicate that so far the RI literature does not have a global reach and as such many places of innovation are not visible in the RI literature as aren't ways how RI would be conceptualized and instrumentalized. Not being open access might be another problem for a global reach. Given that innovation products seem to reach global market at an ever increasing speed and give the establishment of a technology facilitation mechanism that is to support the sustainable development goals and which will be *"based on a multi-stakeholder collaboration between Member States, civil society, the private sector, the scientific community, United Nations entities and other stakeholders"* [69] we posit our findings to be problematic. There are many opportunities for the RI discourse to be globally relevant and for interested parties to get involved especially if the establishment of a technology facilitation mechanism is established in the way outlines in the outcome document [69].

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Consideration of Health Capability Paradigm to Ensure Equitable Protection through Indian National Tuberculosis (TB) Prevention Program[23]

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Abstract

Tuberculosis (TB), caused by bacteria (*Mycobacterium tuberculosis*), usually affects the lung. Being airborne, TB has been one of the world's deadliest communicable diseases. In spite of being curable and preventable, the disease has always been a continuous threat to human population. Moreover, there are cases of multidrug resistant (MDR), extremely drug resistant (XDR) as well as HIV associated forms. Recognizing this grave threat, the World Health Organization (WHO) urged every country to have a national program for tuberculosis prevention and control. After incidences of involuntary detentions of people with suspected TB in some places, WHO (2010) also recommended that national TB prevention programs should incorporate ethical considerations in them. Specifically, it prescribed that human rights and social justice issues should be given due considerations. Studies suggest that India, following the international recommendations, has rolled down a national program to prevent and control TB cases in the country. However, neither is there much consideration of ethics in it, nor there is any pronounced effort to

[23] The earlier version of the paper entitled "Ethics in Indian National Tuberculosis Prevention Program and Strategy: A Social Justice Perspective" was presented in 16th Asian Bioethics Conference held at St. Paul University Quezon City, Philippines on and from 3-8 November 2015.

include social justice issues. The present paper investigates how the inclusion of elements from social justice theory can actually help India's TB program to address the issue of equitable protection. Specifically, it shows how insights from JP Ruger's 'Health Capability Paradigm' can help India's TB strategies to render equitable protection by addressing health inequities (218 words).

Key Words: Ethics, Health Capability, India, Tuberculosis

Introduction

This paper considers the fair provision of equitable protection to the socio-economically vulnerable as one of the foremost and crucial reasons for need of ethics in Tuberculosis (TB) prevention program and strategy. The paper argues that insights from the social justice ethical framework, more specifically, Jennifer Prah Ruger's theory of 'Health Capability Paradigm' (2009) can actually help TB prevention program and strategy to address the issue of equitable protection. Keeping Indian TB prevention programs and strategy in focus, the paper argues that TB prevention and strategies need to adhere to ethical guidance to address health inequity at the level of health capability.

To argue this, the paper is summarized in three sections; **Section I** briefly explains the biological features of TB and introduces global TB prevention strategies. It also deals with the ethical considerations in TB prevention and sets the argument to consider the fair provision of equitable protection to the socio-economically vulnerable as one of the foremost and crucial reasons for need of ethics in Tuberculosis (TB) prevention program and strategy. **Section II** describes the TB prevention policies and strategies in India, points out the gaps and loopholes, highlights the ethical lapses in the existing strategies to ensure fair provision of equitable protection. **Section III** explains the social justice theoretical framework of Health Capability Paradigm (HCP) and grounding in such theoretical framework puts forth the necessary recommendations to address the issue of equitable protection at the level of health capability. It proposes and argues that adopting a guiding vision of 'health as a capability', and incorporation of measures grounded in social justice can bring the desirable changes in the TB prevention program and strategy of India. Finally, the paper concludes with the note that from 2016 onwards when the whole world is moving towards making TB prevention and eradication as one of the sustainable development goals (SDGs), addressing the issue of equitable protection by attending the underlying risk factors of TB related health capabilities become ethical imperatives. For, as part of public health obligation, complete eradication of TB from the world population necessitates addressing the deep rooted barriers of TB related health capability but not just the barriers of TB related health outcomes.

Section I

Risks of outbreaks from infectious diseases, the socioeconomic ramifications of an infectious disease spread, and the preventive responses from a public health system, have always been important elements in shaping national public health policies. However, the possibility of sustainable TB control and eradication presents the need to reexamine the same elements from a different angle altogether. It forces us to reinvestigate the nature and extent of governmental level of preparedness to address the *uncertainty* and the *risk,* and to probe into the vision underlying it.

Unlike many other emerging infectious diseases, TB has been ever present in the human population (1) with oldest molecular evidence dating back to over 17,000 years (2). TB is caused by the bacillus *Mycobacterium tuberculosis* and typically affects the lungs (causing pulmonary TB) but can affect other physical sites such as lymph, bone, and spine giving rise to extrapulmonary TB [24]. Being airborne, the disease is spread when people, sick with pulmonary TB expel bacteria by coughing, sneezing, spitting, etc. (3). In 2014, there were an estimated 9.6 million new TB cases, including 5.4 million men, 3.2 million women, and 1.0 million children. Also, there were 1.5 million TB deaths (with 1.1 million among HIV-negative people, 0.4 million among HIV-positive people) of which approximately there were 890,000 men, 480,000 women, and 140,000 children. Noticeably, of all the infectious diseases, the morbidity and mortality out of TB deaths are unacceptably high, though TB is curable, treatable, and preventable by timely diagnosis and appropriate treatment (Ibid.).

TB, which was once considered to be the disease of the poor (5), gradually, due to its pervasive potentialities and evolution of new strains, has been reconsidered as an endemic disease of the whole world as well as the disease potential enough to explode in epidemic proportions in some parts of the world (2), (3). Consequently, the global biorisk that TB poses has been recognized as a serious public health threat by the World Health Organization (WHO) and other international agencies e.g. United Nations (UN). Nonetheless, three greatest challenges have been recognized to be associated with TB; to deal with drug resistant TB microbes, association of TB with HIV/AIDS epidemic, and the ardent need of innovations both in health system processes and in the tools to combat the disease (3).

The framing of an infectious disease as a *global* and *national* health threat indicates the insistence on a structured governmental response, the allocation of resources, and an overall plan to place the right kind of mechanisms to effectively prevent and control the disease transmission. In 1991, global targets for TB eradication were set. It was followed by declaration of TB as a global public health emergency in 1993 and endorsement of setting of global strategies and targets in 1995 (3), (6). In 2006, WHO came up with Global

[24] Besides, *Mycobacterium tuberculosis*, *Mycobacterium africanum,* and *Mycobacterium bovis* are known pathogenic species capable to cause tubercular disease in humans (4).

Plan 2006–2015 to Stop TB and updated it in 2010. It even identified the desirable components of such a plan, e.g. ensuring testing for drug susceptibility of all previously treated patients and all new patients with known risk factors for MDR-TB by 2015; enrollment of all reported TB patients with MDR-TB (projected at approximately 300,000) on second-line treatment; HIV testing of all TB patients; prompt initiation of Anti Retroviral Therapy (ART) in all HIV-positive TB patients etc. (2). In spite of these initiatives, burden of TB looms large on some countries such as India (Ibid.).This disproportionate burden consequently prompted WHO to include TB prevention and eradication into Sustainable Development Goals (SDGs) from 2016 onwards (Ibid.).

WHO (2010) (7) also recommended that a TB prevention program must include certain ethical considerations to avoid violations of human rights and social justice issues. For, during the TB incidences such as lethal XDR TB emergence in South Africa in 2006, "the Speaker incident" in United States in 2007, health officials were found to adopt drastic public health measures such as forced detention, hospitalizations, isolations, quarantine, short-to-long term detention violating rights and civil liberties (6), (8). The incidences also highlighted that TB patients are more likely to face a detention if they belong to the disadvantaged strata of the society (8), (9). Consequently, for an effective guidance to each member states, WHO recommended that TB prevention should be based upon human-rights approach and should have following considerations; putting individual at the centre of any health policy; identifying, supporting the most marginalized and vulnerable populations; addressing related socioeconomic determinants, their implications for human rights; overcoming institutional constraints and capacity gaps preventing individuals and groups from fulfilling their rights; supporting an integrated response to TB; providing accountability mechanisms; and creating a platform for documenting and sharing best practices (7), (10). WHO has also urged that specific human rights that need to have special considerations in the management of TB, especially MDR-TB are: the right to life; the right to liberty and security of person; the right not to be subjected to torture or to cruel, inhumane or degrading treatment; the right to respect for private and family life; and the right to health (10). Through these recommendations, the four broad ethical considerations that WHO advised to focus are: (a) responsibility and obligation of government to provide free, universal access to TB treatment and diagnosis, to make patients informed about the treatments, as well as to respect the voluntary, informed decisions of patients; (b) duty of health care workers (HCWs) to provide care, support patients' ability to complete therapy, and not to abandon patients. In addition, it also recommended reciprocal obligation towards HCWs to protect their rights of not be infected with TB; (c) implementation of proportional public health measures; and (d) to have evidenced based TB research for enhanced TB prevention, treatment, and quality of care.[25]

Over and above these criteria, the need for inclusion of ethics in TB prevention and strategy has also been argued to address TB related health inequities, which is caused when the threat of TB poses a disproportionate burden on the already socioeconomically deprived groups (7). To these groups, vulnerability from TB gets worsened by the existing *social determinants of health* (SDH) such as poverty, malnourished status, lack of access to healthcare, homelessness, gender, indoor pollution, overcrowding, which cause not only differential exposure to TB but also cause unequal TB infection, disease incidence, and clinical outcome (11). In general, SDHs are known to cause health disparities, i.e., a type of difference in the health status. Health disparities adversely affect the health of population groups who have systematically experienced social or economic deprivations; and positively influences the health status of those who are socio-economically privileged (12), and therefore, are unwarranted, unjust, and to an extent avoidable. The health inequities borne by the SDH are also confirmed by TB experiences (13). For example, during 1990s TB outbreak in the United States, it has been acknowledged that homeless, recent immigrants, injection drug users, and HIV infected persons were more susceptible to TB than others (8). It was also highlighted by a 1991 study that 89% of TB patients at New York's Harlem Hospital did not complete their prescribed course of TB antibiotics either due to personal issues or obstacles in the system (Ibid.). This implies that SDHs, manipulating the health of some groups of people (socioeconomically disadvantaged) play a crucial role in TB outcomes and control. In addition, it implies that they should be essentially considered in TB prevention strategy and policy because they are unwarranted, avoidable, and unjust. However, in many national TB programs and policies such as that of India, neither is there much consideration of ethics in it, nor there is any pronounced effort to render an equitable protection by addressing the TB related health inequities manipulated by SDH.

This paper especially focuses on India and its TB prevention program and strategy. For, though the TB prevention program was initiated during the colonial period, India continues to experience the highest burden of TB in the world even in 2015. Considering it as a failure of public health obligation, the paper reinvestigates the governmental responses to deal with the TB burden in India and puts forward insights to overcome this failure.

Section II

[25] Besides these recommendations, Selgelid (2008) brings to notice that ethics is required for individual obligations to avoid infecting others, third-party notification, and international distributive justice encircling improving access to existing medication, increased R&D for drugs and diagnostics from local to global level.

In 2015, India alone accounts to 24% of global TB cases (3). Annually, it has been estimated that there are 2 million new cases and 300,000 people die from TB in India (14). In 2009, it was observed that in every three minutes, two deaths occur due to tuberculosis in the country (15). In 2002, the number of people succumbed to TB in India was 14 times higher than all the tropical diseases combined (16). In addition, the country witnesses the rising problem of drug resistant tuberculosis (3), (2), (15). With India's TB prevention program and policy being initiated during the colonial period, these issues question the efficacy of TB related public health obligation of the country. Historically, TB prevention in India can be seen to have evolved through three phases: pre-independence phase, before the discoveries of x-ray and chemotherapy; post-independence phase, during which nationwide TB control programs were initiated and implemented; and the phase with the ongoing implementation of WHO-assisted TB control programs (2), (5).

Pre Independence period: This period is marked by the influence of the European sanatorium movement. In India, a Christian voluntary organization founded the first open air sanatorium for treatment and isolation of TB patients at Tiluania, near Ajmer city of Rajasthan in 1906. This was followed by the first TB dispensary in Bombay in 1917. Disease control initiatives in India, including TB, started gaining importance from 1929 through the concerted effort of Red Cross with King George V thanksgiving fund. It gained momentum in 1939, when the TB Association of India was established and a health survey headed by Joseph Bhore prescribed focus on TB and its associated health problems in 1946. In 1948, with support from WHO and UNICEF, a BCG vaccine production center in Guindy, Madras (now Chennai), was set up and in 1951, India started a mass BCG campaign to control TB, which was the first nationwide campaign against TB. This period then ends with the establishment of the chemotherapy center in the country in 1956 (2), (17).

Post Independence Period: This period is initiated with the establishment of a first tuberculosis center of the country and with the roll down of the national tuberculosis control program (NTCP) in the subcontinent. In 1956 with the concerted efforts of the Indian Council of Medical Research (ICMR), government of Chennai, WHO, and the British Medical Research Council (BMRC), Tuberculosis Research Center (TRC) was established in Chennai. It was established with the aim to provide information on the mass domiciliary application of chemotherapy for pulmonary TB treatment in the country. A National Tuberculosis Institute (NTI) was also established in Bangalore in 1959 to evolve a practicable TB program and to make it applicable in all parts of the country, both rural and urban. However, the first comprehensive TB program was started in 1961, when the District Tuberculosis Program was prepared by the government and Anantapur district, Andhra Pradesh was first to receive a model district TB center (DTC). Using this district TB center model Indian government finally launched the National TB Control Program (NTCP) in 1962 (18).

Current WHO-assisted ongoing TB control program: This period is marked by the identification of lapses of NTCP and a revision of such program. In 1992, Government of India, together with WHO and Swedish International Development Agency (SIDA), reviewed the national program and concluded that it suffered from managerial weaknesses, inadequate funding, over-reliance on x-ray, non-standard treatment regimens, low rates of treatment compliance and completion, and lack of systematic information on treatment outcomes. Around the same time, in 1993, when WHO devised the DOTS strategy and recommended all countries to adopt this strategy, the World Bank agreed to provide credit assistance to NTCP, initially for the coverage of a population of 271 million persons, which was later revised to cover a population of 730 million. At present, other bilateral and multilateral agencies, Danish International Development Agency (DANIDA), Department for International Development (DFID), US Agency for International Development (USAID), Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria (GFATM), Global Drug Facility (GDF), and WHO are providing invaluable support to India's TB prevention and control program. To give a new thrust and to revitalize the NTCP, with assistance from the above-mentioned international agencies, the Revised National TB Control Program (RNTCP) was launched in 1997[26]. It formulated and adopted the internationally recommended DOTS strategy, as the most systematic and cost-effective approach to revitalize the TB control program in the country. It emphasized political and administrative commitment to ensure the provision of organized and comprehensive TB control services, reliable and early diagnosis through smear microscopy, an uninterrupted supply of good-quality anti-TB drugs, effective and patient-friendly treatment with short-course chemotherapy (SCC) given under direct observation, and accountability through proper reporting and recording, and thorough and effective supervision. RNTCP was then rolled down to its second phase from 2005 onwards. From 2006, with the aim *"to achieve universal access to quality and patient-centered treatment"* and to *"reduce human suffering and socioeconomic burden associated with TB"* RNTCP was in its third phase by adopting the Stop TB strategy. Along with RNTCP, the third phase of TB control in India is also marked by the adoption of the following programs: Programmatic Management of Drug

[26] More recently, RNTCP, since April 2010, to improve TB case detection, along with World Vision India (WVI) and its 6 civil society partners such as GLRA, ADRA India, CARE India, SHIS, TB Alert and LEPRA India have been implementing Project Axshya in selected problematic areas in West Bengal, Bihar, Jharkhand, Chhattisgarh, Orissa, Madhya Pradesh and Andhra Pradesh, with the assistance of Global Fund Round 9 TB Grant (20).

Resistant TB (PMDT) to combat the rising challenge of the drug resistance in the country; National Strategic Plan (2012-2017) to reach out to those patients who were earlier found to have been missed out by the system; and Social Action Plan (2013) (19) to identify the gaps and barriers in program and system (20), (21).

In spite of its revisions and reconsiderations, Indian national TB control and prevention program has been criticized. It has been blamed to have overlooked and undermined several aspects of TB impacts and is also held responsible to be less sensitive to several issues that require ethical reflections. Some of such aspects are stated below:

(1) RNTCP's expectation was that at least half of the cases should be smear positive, however, many of those diagnosed on x-ray (sputum negatives) revealed not to be TB cases. And RNTCP has been blamed to provide inadequate care to such cases, thereby violating the right to health.

(2) At one point, it was estimated that grossly there was unethical treatment of at least 66% to 74% of the cases as identified by RNTCP, which then violated the obligation to provide the adequate treatment and also hindered the right to life of the affected.

(3) In spite of RNTCP's expansion in the country "to achieve universal access to quality and patient-centered treatment", there are reported delays in procuring drugs, identification, diagnosis, and treatment which thereby questions the duty to provide adequate care. In addition, there are serious lapses in reporting, findings, and analysis of data (22), which affected the evidenced based TB research in the country.

(4) In spite of the global recommendation to protect health care workers from TB (10), on and from 2012 till July 2015, at least 40 doctors in Mumbai, Maharashtra, a western state of India, have reportedly contracted tuberculosis; 20% of them were also diagnosed with drug resistant tuberculosis (23). While, such recurring incidences imply the lack of proactiveness from governmental side, it also questions the onus of RNTCP to have a reciprocal obligation towards HCWs to protect their rights of not to be infected with TB.

(5) Globally, India features with the highest burden of multidrug-resistant tuberculosis (MDR-TB) (20). In addition, there are rising cases of extreme drug resistance and total drug resistance cases. Many times it has been noticed that despite having received treatment under the Revised National Tuberculosis Control Program (RNTCP) for a long period (24), the patient developed extensive drug-resistant tuberculosis (XDR-TB). This rising problem of drug resistant cases in the country is considered as "man-made problem and system failure" (25), (26), (27). This then questions the effectiveness of the program, responsibilities of the government and the public health system of the country.

(6) RNTCP is also found to have been blamed to stigmatize patients. For, the patients, who exclude themselves from the system after adhering to treatment for some time, are often marked as "Treatment defaulter" or "noncompliant". While these incidences make it noteworthy that TB involves stigmatization, ongoing revised TB control program in India is found to have been less sensitive to this issue, thereby, violating the right to health and right to life of the stigmatized.

Over and above these issues, TB infection, control, and prevention in India highlight another issue. Certain groups and individuals in India are found to be more prone to TB disease and these specific groups and individuals are found to be people of lower SES, those living in poor housing, facing poor environmental conditions, food insecurity, indoor air pollution, having less access to health care services, have less or no education, experiencing tobacco or alcohol abuse and scheduled tribe women, and people with co-morbid conditions such as diabetes, HIV/AIDS (28). TB, in India, is also found to affect unevenly the social and economic status of individuals and groups and cast its shadow disproportionately across genders. The socioeconomic impacts of TB in India can be summarized as follows; more than $100 million debt is incurred by patients and their families out of TB in India. More than 100 million productive workdays are lost annually and while more than 3,00,000 children have left school permanently for their parents being infected with TB, more than 1,00,000 TB infected women were rejected by their families (28), (29). According to the National Family Health Survey (NFHS)-3, though TB cases are found to be located more in urban areas, the prevalence of TB is higher in rural areas in India. This regional disparity is sometimes attributed to the lack of TB clinical facilities and health personnel in rural areas. In addition to this, it has been observed that while two-thirds of TB cases are male, TB takes a disproportionately larger toll among young females, with more than 50% of cases occurring amongst females less than 34 years of age in India (29). These groups and individuals being affected more than others, it implies that there is a significant relation between SDH and TB related health disparities in India. Well known SDH in India, manipulating TB disease, are found to be poverty, caste, gender, geographical region, literacy, nutrition, water and sanitation, health expenditure, and inadequate health care services (30), (31).

With these known facts and figures out of TB in India, India's TB prevention program and strategy were expected to be sensitive to these issues. However, on the contrary the national TB prevention program and strategy in India have undermined these issues. Rather, the program has focused more on the implementation of DOTS as a core strategy (with 46% domestic share, 54% donor share), in sorting out the inadequacies in the treatment regimen, supply, drug intake, by being influenced by the international agencies and disregarded the indigenous health inequities based on differing health needs of the citizens of the country. To address these inadequacies, national level initiatives have been taken to strengthen, improve, expand, and deploy the resources through the implementation of the strategy of mandatory notification of TB cases. And a normative, entitlement-based

grants, outcome-based budgeting, testing services in all PHCs have also been introduced (32). However, it has been done as part of legal obligation, but not with ethical insights. Under this RNTCP, the aim to end TB in India or the 'Zero TB' concept, though, has been introduced, its focus has been always on the funding side. There has been no acknowledgement and scope of the potent role of SDH that they may play in the onset and spread of TB exposure, infection, and disease on groups and individuals, though the aim was adopted to "reduce human suffering and socioeconomic burden associated with TB". The Social Action Plan (SAP) though have been introduced in 2013, its aim has been ensuring universally accessible service delivery (19), that is, to provide opportunities but not focusing on enabling such opportunities. It also overlooks the utilization abilities of individuals and groups to access and afford these opportunities provided. This paper argues that through these gaps and loopholes of RNTCP, TB related inequities may pass through to cause greater health inequities, if this issue remains unacknowledged and unaddressed in RNTCP and its allied programs. And to address these inequities, this paper claims that RNTCP requires the guidance of a theoretical-ethical framework. For, being grounded in such theoretical-ethical framework, RNTCP can address inequities by addressing TB related SDH, can ensure and enable equitable provisions of TB related health care services, can have a proper underlying vision, can avoid violation of the right to health and life, and can also address several other issues arising out of RNTCP.

The need for an ethical guidance to TB control and prevention program in India has been recommended by some literature as well. For example, while some suggested adhering to *Due Care* (22) framework, others suggested Reciprocal Obligation (33) or Relational Autonomy (34) to render the public health obligation. Some others have suggested following *WHO Ethical values* (35), the principle of *Primum non nocere* (24) or the public health framework of Principlism (36), (37). However, gaps remain in the literature for having less or no causal link between increased vulnerability in a population and the existence of SDH in relation to TB incidence and prevalence. Moreover, though the above mentioned literature highlighted the ethical aspects of TB outbreak and control program in India, the concern of equity is relatively under discussed in them. It is also noteworthy that in these literary sources, there is a lack of recommendation of underlying vision and that of a comprehensive framework. This paper claims that the social justice theoretical framework of Health Capability Paradigm (HCP) can guide RNTCP in this regard. Next section, with explanation of HCP delineates how a comprehensive HCP can help RNTCP to address this issue.

Section III

Rooted in human flourishing, the social justice theoretical framework of HCP values health intrinsically. It gives special moral importance to health capability, that is, a person's ability to be healthy, which recognizes two proxies; health functioning, or health performances, and health agency, or the ability to lead a life one values. As a theoretical framework, it values "central" health capabilities that is, the capabilities to avoid premature mortality and escapable morbidity. This view of central health capability employs "shortfall equality" to judge public policies affecting health. Shortfall equality compares shortfalls of actual achievement from the optimal average (such as typical longevity or physical performance) (38).

As a social justice framework, HCP focuses on vulnerability and insecurity. It is concerned with *"individuals' exposure to risk and their ability to adequately manage it…"* (39). According to HCP, people become vulnerable and insecure when they lack access to necessary health care services and several socioeconomic, individual factors affect the accessibility, availability, quality, and utilization of health care services (40), (41). As some groups and individuals are more affected by these, as a consequence, inequities are caused, but these inequities are caused at the level of health capabilities, specifically, in central health capabilities (40). These health inequities, according to HCP, prevent people from achieving good health. As they arbitrarily, unnecessarily reduce the capability for health functioning and especially affect central health capabilities, they are social justice failures and are to be considered as unjust, unwarranted, and avoidable (42).

HCP values human diversity and favors those below the maximum average over those above it. In favoring that, HCP requires, shared health governance, a construct which promotes voluntary ethical commitment and shared responsibility by all, those more fortunate and those in need, to ensure and enable health capability for everyone (Ibid.). In other words, it is a construct in which individuals, providers, and institutions work together to create an environment enabling all to be healthy, by ensuring and enabling access to high quality care through "medical appropriateness" and "medical necessity" (Ibid.). HCP proposes that quality of health care can be judged by its ability to address functional impairments arising from injury or illness. And the impact of health care on individuals' health capability is assessed by examining health needs, health agency, and health norms (Ibid.). While health needs are directly observed through health functionings; a health agency is judged through the shortfall of actual achievements from an agreed-upon optimum. And health norms are *"societal norms about health that govern the environment in which individuals navigate choices for healthier life"* (43). To address inequities in health capabilities, to help people to transform healthcare resources into optimal health functionings, these norms, according to HCP, need to be closely scrutinized, because norms can be either positive or negative.

This paper argues that this social justice theoretical framework of HCP and its insights can be

extended to TB prevention and mitigation strategies. TB negatively affects an individual's perception of his/her own health in various domains, including physical, mental, psycho-social, and economic well-being. From an HCP perspective, TB thus affects the health norms and health agency. One's susceptibility to TB is increased with poverty, characterized by poor health, compromised immunity, exposure to unhygienic conditions, and inadequate nutritional intake. And once acquired, the physical effects of tuberculosis cause debilitating impacts on the lungs, appetite loss, weakness, weight-loss, and even cause death (28). In terms of HCP, being unable to avoid these conditions, TB affects health functioning and central health capability of individuals. And when the manifestation of TB significantly hinders an individual's physical capacity to engage in routine activities, including those related to livelihood and income generation, TB sabotages one's ability to work and it deprives one's health capability (44). With disproportionate impacts of TB on health functionings, health agencies, central health capabilities, and health capabilities of some groups and individuals, TB causes inequity at the levels of central health capability and consequently, at the level of health capability. And to address that, this paper argues that RNTCP requires the insights of the social justice theoretical framework of HCP. For, addressing inequities in central health capability as the foremost goal of HCP, it brings with it the need for attention to the SDH-caused TB related inequities at the level of central health capabilities and disparities in health capabilities. By focusing on these, TB prevention and program can better achieve its goal of fair provision of equitable protection and can also address several other issues as a comprehensive framework.

Recommendations

With insights from the social justice theoretical framework of HCP, this paper recommends some measures for RNTCP.

• RNTCP should reconsider the underlying vision of health to ensure and enable conditions to avoid escapable TB. With a foundation on HCP, RNTCP should consider health as a capability to avoid TB related escapable morbidities and mortalities. Such a vision can guide RNTCP to address the inequities at the levels of TB related central health capabilities as well as in health capabilities, and can also make provisions to avoid violation of the right to health and life.

• Grounding in HCP, RNTCP should consider focusing on both TB related health outcome and health agency, but not just on TB related health outcomes. Focusing on both would make a scope in RNTCP to equitably assess the TB related health performances and utilization of TB related health care services by individuals and groups.

• With the foundation on HCP, RNTCP needs to ensure and enable vertical as well as horizontal equity, by identifying the pockets of the shortfall at the groups and individual levels. This can also lead RNTCP to address the barriers at the level of TB related health capability. And for this, the concept of shortfall equality of HCP can guide RNTCP. Strategically, this implies collaboration of RNTCP with other sectors and other health care programs, risk estimation and assessment, and improved surveillance of service delivery and utilization from national to block levels.

• HCP also suggests SAP/TAP (2013), a subsidiary program under RNTCP, to undergo some changes. It suggests ensuring and enabling a bottom up approach, rather than focusing solely on ensuring accessibility to some selective groups. This implies, addressing the indigenous health needs, rather than being influenced by the international agencies exclusively. It also implies ensuring and enabling a provision of high quality diagnostic and treatment services at the primary level of health care service delivery.

• As mentioned earlier, TB in India involves stigmatization and discrimination. In this matter, HCP recommends RNTCP to modulate TB related social norms and, thereby, health norms in cooperation with varied stakeholders.

• Grounding on HCP, RNTCP should also exercise a collective responsibility. The HCP concept of shared health governance can help RNTCP in this matter. At the practical level, this implies collaboration with different stakeholders of RNTCP such as TB infected patients, doctors, health care workers of different levels, marginalized groups, including tribal women, different research institutes to have a collaborative decision making, to develop a shared consensus, and to ensure and enable the highest quality of TB treatment from block to national level.

Conclusions

Tuberculosis infection is an airborne infection. The risk, thus, depends on the concentration of tuberculosis bacilli in the inhaled air and the duration of exposure. Early case detection and effective treatment not only cures patients, but interrupt the transmission of tuberculosis in the community as well (5). While anyone can contract TB, it predominately affects those who are situated in the lower stairs of the socioeconomic ladder. It is most prevalent among marginalized, discriminated populations and people living in poverty, however, it can also exacerbate poverty.

The foundation of this paper is on the social justice theoretical framework of HCP. Grounding in that and with a focus on India's RNTCP, it argues that: (i) the vision of health needs to be changed to health as a capability in the RNTCP, and (ii) to equitably consider the socioeconomically disadvantaged people in TB control and prevention program, there is a need of reconsideration of RNTCP. With such reconsiderations, the paper claims that RNTCP can have a greater concern of preventing escapable TB disease and premature TB deaths and can also deliver equity in TB detection, diagnosis, treatment, and at the level of TB related health capability.

As a concluding remark, the paper comments that from 2016 onwards, when the Millennium Development

Goals (MDGs) are transforming to the Sustainable Development Goals (SDGs) (2), complete eradication of TB from the world population, necessitates addressing the deep rooted barriers of TB outbreak, incidence, and prevalence. And this implies addressing the barriers at the level of TB related central health capability and health capability as part of the public health obligation. For, addressing the underlying risk factors of TB related health capabilities become ethical imperatives to render an equitable protection to all.

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Differences in gender and educational stage in the emotional skills during teacher training

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Abstract

The aim of this study is to assess the level of self-realization and personal growth of teachers in training in two Spanish Universities, one located in the north, University of La Rioja, and other in the south, University Catholic Murcia. The sample consists of 366 teachers who were in training, 183 future primary teachers belonging to the University of La Rioja, and 183 future pre-school teachers at the Catholic University of Murcia. The "Questionnaire Self-concept and realization", AURE, (Aciego et al., 2005; Dominguez, 2001) is used, and the results show that future primary school teachers, which teach students between 7 and 12 years old, show favorable levels in self-realization and personal growth. However, these measures are significantly lower compared to future teachers of pre-school education, that teach students between 3 and 6 years old-. Differences in variables are also produced by gender, significantly higher in the future women teachers of pre-school. These data indicate a more urgent need to strengthen programs based in emotional skills, in particular programs such as Mindfulness among men, and among those who teach the older students.

Keywords: Self-realization, Personal development, Emotional skills, Teacher training, Mindfulness, Gender and Educational stage.

Introduction

The need for integrally training all the educational community members in emotional skills and especially to teachers is a priority key in education (López-Hernáez et al., 2014). Bisquerra (2009) and López-Goñi et al. (2012) describe the inclusion of emotional competencies in initial teacher training as a fundamental, although, in practice, they are secondary in the set of teaching skills.

The development of emotional skills in a teacher means an improvement in their interpersonal relationships and their education efficacy (Bisquerra, 2007). Emotional competencies are defined as necessary to be a good teacher (Vaello, 2009), because the most personal and emotional facet, based on the awareness and ability to manage and control one's emotions and feelings, is directly related to interpersonal relationships with others and it represents a basic element in the motivation to face the teaching-learning process (Soriano et al., 2008).

Gallego et al. (2004) note that the appropriate emotional management and the harmonization between the cognitive and emotional, should be fully considered in the curriculum. Jennings et al. (2009) and Sutton et al. (2003) show the close relationship between social and emotional competencies of teachers and the effectiveness and quality for developing processes of teaching-learning in the classroom and to promote prosocial behavior of students in class. The university context is a privileged space for the promotion and development of emotional skills, contributing positively to the personal and social welfare of students (Livia et al., 2015) and an ideal study environment for identifying and evaluating them (López-Goñi et al., 2012).

A study of Zuazua (2001) shows that most young Basque Professional Training students claim to have a full life and have more luck in their life projects; however, only those with higher levels of self-efficacy generate higher expectations of themselves, they trust their capabilities, they perceive the academic environment as less threatening and are adapted successfully to the demands, experiencing higher levels of general welfare (Cabanach et al., 2010). Pertegal et al. (2009) show that most of the students are not prepared for successful employment integration in terms of emotional competencies are concerned.

According to Marchesi et al. (2007), 77% of teachers are satisfied with their life and career, although a 75% feel that the profession has worsened in recent years, generating a growing discontent. This malaise affects the concept that the teacher has of himself, causing him insecurity and lack of self-esteem (Hue, 2008). In this sense, Pena et al. (2012) have found a significant relationship between emotional competence in primary-school teachers and the different dimensions of burnout and engagement, thus, greater emotional competence by teachers involves a lower level of exhaustion, in addition to higher levels of personal fulfillment. Peñalba et al. (2013) found that one in two student teachers have a deficit in emotional competencies, including personal and interpersonal skills; although their skills in this area are higher compared the University population in general (Bueno et al., 2005).

Personal maturity allows teachers to be more self-aware, to perceive better and have a deeper understanding of what they do and its effects (Ramírez et al., 2012). The teacher who is emotionally more competent is better prepared to engage in a positive and appropriate manner with the educational community, which increases the efficiency of education (Bisquerra, 2007), the learning process,

mental and physical health, the quality of social relationships and the academic and work performance of the educational community (Brackett and Caruso, 2007; Extremera et al., 2004). Teachers with highemotional skills experience higher levels of general welfare (Cabanach, et al., 2010) and they act as agents of social change in their educational experiences (Leguizamon, 2014).

Gender difference and emotions

"Gender differences are not natural, but historical-cultural constructs that express power relationships based on differences that distinguish the sexes" (Monzón, 2004, p.8). Children are born neutral psychosexually and can be assigned to one or other gender during the first years of their lives, with only a change in the practice of learning (Money, 1988).

Gender is not a natural quality of people but rather a complex set of cultural beliefs mutually related which stipulate the social meaning of the masculine and the feminine, concept that varies across cultures and across time (Gaviria et al., 2013). Throughout history, women have played a secondary role in society being relegated to the family, or small circles of friends, so they have learned to express their emotions in intimate places, being more prepared phylogenetically to express their emotions while men socialize to express a greater extent physical force (Subirats, 1997).

The relationships of the girls are more comprehensive and they have a different sense of life project and self-realization to men (Zuazua, 2001). Professionally, women opt for employment models that represent greater harmony in the interaction between work, family and community (Mojerón, 2010). In this sense, the study of Pegalajar et al. (2015) shows that future female teachers have more positive levels of self-realization and personal growth that male teachers, and tend to get significantly higher scores than men on emotional intelligence measures (Bueno et al., 2005; Extremera et al. 2007; Joseph et al., 2010; Valdez et al., 2010).

Recent studies on cyberbullying relate a greater attitude toward violence and reduced capacity on emotional skills on men. There is a higher prevalence of men as large cyberbullies (Sabater et al., 2015, Garaigordobil et al., 2013). This fact is transferred to traditional bullying, where the prevalence is higher among boys, which harass more physically than girls (López-Hernáez, 2013; Ortega, 2008). In general, boys are more interested in controlling external events, being more aggressive physically and with greater domain to their peers (Anastasi, 1982).

Professional choice and emotions

An effective personality is linked to a more mature vocational decision making based on the best knowledge of the person and the labor market (Bethencourt et al., 2011). A study by Mejia et al. (2011) shows how some future teachers have not covered their emotional needs and self-esteem. In this sense, Peñalba et al. (2013) also found how one in two student teachers shows a deficit on emotional competencies, including personal and interpersonal skills; although the skills in this area are higher compared to the general student population (Bueno et al., 2005). According to Pertegal et al. (2009), most students are not prepared for successful workplace integration, because they do not have sufficient skills to the relationship with others, nor to adapt to continuous change, nor to control their emotions.

The teaching profession has a low social and economic status in many countries, and it is difficult for them to achieve a similar status to that of other professionals with careers traditionally more dilated, as doctors or lawyers (Garcia-Garduño, 2010). Almost half of the student teachers do not study because of a strong vocational interest, they have expectations to abandon the degree and make another (Garcia-Garduño et al., 2006), with an unfavorable attitude towards it. According to Mendías et al., (2004), the main reason why the future teachers of pre-school education choose this degree is because they like young children.

Moreover, according to Garcia-Garduño (2010) it is the intrinsic interest, satisfaction for a job well done and personal achievement, which leads most teachers to choose this profession. The teaching vocation and family influence, especially having teacher's relatives, are the main reasons why the degree of education is chosen (Garcia-Garduño, 2010; Pegalajar et al., 2015). Family involvement is essential in the process of self-regulation and academic vocational choice of their children, as it affects significantly and positively on the perception of their competence as students (Gonzalez et al., 2002).

The study of Pegalajar et al., (2015) aims to assess the level of self-realization and personal growth of student pre-school teachers at the Catholic University of Murcia (n = 183). The questionnaire results of -AURE- (Aciego et al., 2005; Dominguez, 2011) show that future pre-school teachers show very favorable levels of self-realization and personal development, mainly in behaviors of sociability, respect and collaboration. Participants are themselves quite motivated and show efficiency in planning tasks, and most of them express high levels of effort and persistence, seeking alternatives, they are tolerant and autonomous, and they enjoy on the realization of their projects. These results are much more positive in the case of the female students.

Therefore, the objective pursued in this research is to know what results are obtained at the University of La Rioja, compared to the study conducted on the Catholic University of Murcia (Pegalajar et al., 2015) using the same methodological framework (planning fieldwork techniques and instrument). It aims to determine the level of self-realization of future teachers of primary education, and whether gender affects this self-realization. Finally, it is performed a comparison between both samples, to find out if there are differences regarding to the educational stage

(pre-school and primary education) and gender (men and women) between them.

Methodology

Sample

The population is composed by student teachers of all courses with a primary education degree at the University of La Rioja, and a total of 183 students completed the questionnaire. The selection of subjects was performed using a simple random probability sampling (Tójar et al., 2009) by selecting all subjects who were in the classroom at the time the survey was conducted. For the calculation of the sample, it was used the formula for communities with fewer than 100,000 subjects with a confidence level of 95%, and a maximum estimation error of 5%.

In relation to the composition of the sample, gender is distributed with 68% being women, compared with 32% of men. Their ages are between 18 and 39 years, predominantly from 18 to 21 years (76%), followed by the range from 22 and 25 (18%) and the range from 26-39 years (6%). The majority origin is the autonomous community of La Rioja (85%) with a wider segment residing in the capital and surrounding municipalities (71%). However, it should be noted that 15% came from other regions. In the distribution by courses, there were more in the first year (36%), followed by the third year (31%), second year (22%) and fourth year (12%). Most have studied in public schools (74%). In general, they live with their family or with peers (92%), are interested in culture, to read and to travel (97%) and a significant percentage of them, do sports regularly (67%).

Instrument

The methodology is quantitative and it is based on the technique of standardized statistical survey. The data collection was performed through the questionnaire AURE "Questionnaire Self-concept and realization" -AURE- (Aciego et al. 2005, Domínguez, 2001) which includes 55 items grouped into six factors: Self-Concept, Projects, Attitude towards Work, Friendship and Love, Social Concern and Ego Strength. Each item is measured on a Likert scale, whose answers are between 1 and 5 (representing 1 = strongly agree, and 5 = strongly disagree). The application time is short and the questions are simple, which makes its application be an advantage.

The questionnaire meets high standards of reliability, because the coefficient obtained through Cronbach's alpha (.97) and Spearman Brown for unequal halves (.93) prove it. Besides analyzing the factorial structure, it provides an understanding of the contents able to reorganize its into three major factors, such as: 1) Coping, operability and fulfillment in the work: includes aspects of planning, availability and self-control against the task and the norm; 2) Self-concept and self-esteem, which compiles all aspects related to the evaluation of himself, and 3) Empathy and social fulfillment, that refers to the satisfaction in relation to others, concern and communication with others.

Procedures

For the application of the questionnaire to the sample, we contacted the faculty of the University of La Rioja teaching different courses by email, indicating to them the objectives of the investigation and requesting the necessary authorizations to access the study sample.

To get a correct application of the instrument, the students were informed about the rules for completion, the questionnaire characteristics and purpose of the test. The questionnaire was administered individually, during school hours within the Faculty of Letters and Education, thanks to the collaboration of the responsible teachers for compulsory subjects in each group.

Analysis of data

For the statistical processing of the data SPSS was used, version 21 for Windows and it performed a descriptive and correlational analysis of the results obtained from the various dimensions of the questionnaire. We have implemented the Student t test for comparison of means to demonstrate the existence of significant statistically differences between the scale factors and the variable "gender" of the participants, besides the Levéne test to know equality of variances. All analyzes were calculated with a confidence level of 90%.

Results

Regarding the ***first objective***, which aims to determine the level of self-realization of future teachers of primary education, the results are shown in Table 1. The mean scores and standard deviations are reflected, for each of the dimensions of the questionnaire, showing generally favorable levels of self-realization and personal development.

Table 1. Analysis of mean (M) and standard deviation (SD) by factors at the University of La Rioja (n = 183).

Dimension	M	SD
Friendship and Love (FL)	1.89	.935
Self-Concept (SC)	2.21	.902
Social Concern (SC)	2.22	.936
Attitude Towards Work (ATW)	2.30	.994
Ego Strength (ES)	2.38	.994
Projects (P)	2.38	.886

It is in the *"Friendship and Love"* dimension where the best scores are obtained, which means a good future teachers behavior towards others, in relation to variables sociability, communication, respect, cooperation and identification; as well as other towards them, while they declare receive affection, positive assessment, to feel respected and get support and assistance.

It is also quite favorable for their valuation to the dimension *"Self-Concept",* at the level of personal satisfaction, overall personal assessment, physical, intellectual ability, mood, social interaction, confrontation with reality and regulatory adaptation. Participants show at the same time, a high *"Social Concern"* with active participation in social problems, together with their high *"Attitude towards Work",* concerning their availability, motivation and achievement assessment, such as planning, and precision of action and evaluation of work.

However, the dimensions *"Ego Strength*" and "*Projects*" are valued lowest by the participants. The future teachers of primary education, show lower values as to their availability to the effort, perseverance and persistence on the task, tolerance and patience with the difficulties, self-control and searching for alternatives. It is the same with the dimension centered on the potential of enjoyment and the adequacy of projects carried out, although it is focus more towards agreement, since scores are placed closest to the middle of the range.

Regarding the ***second objective***, which seeks to ascertain whether the gender variable affects the personal development of the participants, statistically significant differences are detected in some of the study variables, listed in the following tables.

Table 2. Means and standard deviation of variables "Self-Concept" by gender*

Self-Concept	Gender		Sig. t
	Men M (SD)	Women M (SD)	
SC4. I feel very capable	2.00 (.90)	2.39 (.78)	.003*
SC7. Physically I am strong	2.52 (.84)	2.98 (.99)	.003*
SC18. I am hard-working	2.36 (1.04)	1.91 (.95)	.004*

* Only statistically significant variables are shown, <= 0.05 ((in each table)

In general, the self-concept of men is higher than women, feeling more capable and stronger physically. However, the girls claim to be more hard-workers.

Table 3. Means and standard deviation of variables "Friendship and Love" by Gender*

Friendship and Love	Gender		Sig. t
	Men M (SD)	Women M (SD)	
FL2. I tell my problems to friends and family	2.22 (1.01)	1.84 (1.0)	.017*
FL3. I am interested in problems and illusions of my friends	2.02 (.89)	1.58 (.99)	.005*
FL4. I do not like to mock others	2.76 (1.07)	2.38 (1.20)	.039*

Participating women report a higher level in the dimension "*Friendship and Love*" in relation to men, since they have more emotional empathy in your relationship with others. They care more about the dreams and problems of others, communicate more with their close people and do not like to make fun of others.

Table 4. Means and standard deviation of variables "Attitude towards the task" by gender*

Attitude towards the task	Gender		Sig. t
	Men M (SD)	Women M (SD)	
ATT2. Facing a new task or job I think I am able to do this and I act with confidence	2.14 (.93)	2.49 (.99)	.024*
ATT3. I prefer tasks that involve new challenges and difficulties	2.24 (.87)	2.66 (.97)	.006*

Generally men feel more capable and more confident before a new task that involves new challenges and difficulties than women.

Table 5. Means and standard deviation of variables "Projects" by gender*

Projets	Gender		Sig. t
	Men M (SD)	Women M (SD)	
PR4. I usually have fun just imagining things I could do	2.36 (1.00)	2.01 (.91)	.019*

Table 6. Means and standard deviations by factors at the Catholic University of Murcia (n=183)

Dimension	M	SD
Friendship and Love (FL)	1.77	.542
Attitude to the task (ATT)	1.95	.608
Self-Concept (SC)	2.04	.520
Ego Strength (ES)	2.18	.690
Projects (P)	2.20	.563
Social Concern (SC)	2.22	.826

Source: Pegalajar, Mª.C. and López-Hernáez, L. (2015)

Participating women have a higher level of imagination than men. However, no statistically significant differences were observed according to gender in any of the variables belonging to the dimension "*Social Concern*" and *"Ego Strength".*

The ***third objective*** aims to determine whether the educational stage and gender affect the personal development of teachers._For this, we have made a

comparison between the University of La Rioja (UR) and the Catholic University of Murcia (UCAM). Relating to the ***educational stage***, students of pre-school education at the Catholic University of Murcia obtained significantly higher scores to students of primary education at the University of La Rioja.

Comparing Table 7 and Table 1, the results observed are closer with the dimension "*Love and Friendship"* appearing in both cases first. In the dimension "*Social Concern*", both samples share the same mean. However, it reflects how future pre-school education teachers (Catholic University of Murcia) show much more favorable mean in every one of the factors, with a lower deviation of the data with respect to future primary education teachers at the University of La Rioja

Regarding to the ***gender*** variable, significant differences are shown in most dimensions in both samples. In Table 7, it is seen as the UCAM (pre-school future teachers) women participating obtained highest score, except in "*Self-Concept*" and "*Ego Strength*." However, at the UR (primary school future teachers) the significant differences are present in dimensions *"Self Concept", "Friendship and Love", "attitude towards the job" and "Projects*" (but only in some variable and no in the overall dimension), and there are no differences in any of the variables referring to the dimensions "*Social Concern"* and "*Ego Strength*." These data demonstrate that the influence of gender in personal fulfillment is greater in pre-school future teachers than in primary education future teachers.

Table 7. Means, standard deviations and global significance in UR and the UCAM

Dimension	UR			UCAM		
	Men M (SD)	Women M (SD)	Sig. t	Men M (SD)	Women M (SD)	Sig. t
Self-Concept	2.12 (.86)	1.98 (.86)	.316	1.94 (1.00)	2.04 (.50)	.055
Friend-ship & Love	1.86 (.85)	1.66 (.80)	.115	1.98 (1.26)	1.76 (.49)	**.001 ***
Social Concern	2.43 (.76)	2.30 (.84)	.297	3.23 (2.91)	2.18 (.61)	**.000 ***
Attitude to the task	2.36 (.87)	2.16 (.77)	.114	2.08 (1.02)	1.95 (.58)	**.046 ***
Projects	2.29 (.71)	2.34 (.70)	.675	2.22 (.97)	2.20 (.54)	**.018 ***
Ego Strength	2.28 (.87)	2.33 (.80)	.669	2.07 (.85)	2.18 (.68)	.656

Discussion and Conclusions

In conclusion, both future teachers of pre-school education and primary education, have high levels of self-realization; however this is significantly lower in the primary education teachers, so they seem to need additional support in their emotional skills acquisition. In this sense Mejia et al. (2011) propose emotional teacher training, integrated into the mandatory content of the curriculum, with the main responsibility to support future students in the development of their personal autonomy.

The skills involved with emotional intelligence are focused on the ability of the person to become aware of himself as well as in the management and recognition of their own emotions and motivations and those of others (Goleman, 1995). Salami (2010) affirms the importance of designing programs to promote psychological well-being in university students as a means of improving the quality of teaching and the development of programs to improve their affective-motivational resources for a better self-acceptance and personal fulfillment.

Gender influences personal fulfillment of future teachers, women show higher levels of personal achievement than men, and even more future pre-schools women teachers. In this regard, Sanchez et al. (2008) show that women score better on issues related to the relationship with the other. So, further works is needed in emotional skills with men, and to reflect on the need to encourage the creation of new education programs for equality at all levels, along the lines set by Díaz-Aguado (2009). These results confirm the need for more female qualities to positions of responsibility, thus affecting positively the development of social work organizations (Ramos-López, 2005).

The study shows that the choice of educational stage is also determined by the emotional capacity of teachers, future teachers with more favorable levels of self-realization and personal growth, choose pre-school education and they also have a higher vocation (Pegalajar et al., 2015). According to De León et al. (2008), university students who reported higher levels of personal growth, has more capacity for a correct career choice. A greater capacity for professional choice is consistent with the purposes of the degree chosen, related to a good academic performance and a more favorable attitude (García-Garduño, 2010).

Nelis et al. (2009) found that young adults who participated in an intensive emotional training had improved their levels of emotional intelligence, maintaining this improvement six months later. In this sense, the implementation of programs that work emotions in schools, for example, mindfulness techniques in the educational community, show very positive results in personal development and academic of their participants (López-Hernáez, 2015). However, its implementation is not without its limitations, so it is proposed to increase the duration of these programs and teacher training, among other guidelines for improvement (López-Hernáez, 2015). Studies of the practice for emotional and personal development "Mindfulness" offers promising results, encouraging educational institutions to integrate its in academic training, for beneficial results in emotional well-being, ability and learning potential and physical health and mind of those who practice (Burnett, 2011).

In recent decades "Mindfulness" training has been introduced in numerous health improvement programs and various psychological treatments (Miró, 2007).

Franco et al. (2011) have shown that these programs are valid and appropriate to promote personal growth and self-realization of those who perform it. Kuyken et al. (2013) showed the acceptability and effectiveness of program Mindfulness, reporting improving of mental health and well-being factors such as coping tasks without fear and with enjoyment, self-esteem and empathy. It would therefore be advisable to implement programs like Mindfulness in the curriculum of the Faculty of Education, since the school landscape and current professional requires the involvement of different educational agents, beyond the mere transmission of academic content; teachers should be aware that their participation has to contribute to the overall development of students and their future professional performance (Álvarez et al., 2011).

The main limitations of this study are the sample size, however the strength is the diversity in the origin of the participants, and it would be reasonable to try out programs to lessen the observed gender gaps and gap between these two groups of teacher trainees in order to improve the outcomes of the training programs to provide enthusiastic and mature teachers.

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Analyzing Bioethics Curriculum in Korea

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1. Introduction

There is a global agreement that bioethics education should be provided to citizens at all levels, which explains why UNESCO has promoted the education of ethical issues of science and technology (Macer, 2008). In Korea, too, bioethics education has become popular as the Ministry of Education required to include some bioethical issues as a part of the life science in junior and senior high school education.

At the university level, however, the contents of bioethics education tend to reflect lecturers' personal views because there is no mandated textbook. Until now, most bioethics education is largely provided to medical and nursing students. Without shared philosophy and determined lecturers, therefore, it is not easy to offer bioethics education related courses to general students.

As Kim (2006) claims, Hwang Woo-Suk scandal has confirmed that ordinary citizens as well as researchers and physicians need to have a certain level of proficiency in ethics and bioethics in order not to be distracted by sensationalism in mass media. To achieve this goal, education is imperative. For a more vital educational system, it is necessary to understand present situations and problems.

Therefore, this study tries to find out current conditions of bioethics education in Korea by presenting bioethics curricula in junior and senior high schools, and two selected universities, which will be able to show the (dis)continuity of underlined philosophy in bioethics education. And then it aims to provide some suggestions as final remarks.

2. Bioethics education in high school

1) Junior high school

Bioethical considerations in Korean high school education have been directly or indirectly addressed in diverse subjects such as science, Korean, Morals, Social Studies, Technology and Home Economics (Park et al., 2005). Among others, however, it seems to be clear that moral education is most closely related with bioethical issues (Kim, 2006: 55).

Table 1 shows that contents of Morals in junior high school are divided into four areas including personal life, family·neighbor·school, social life and nation (the 7th Curriculum; in Han, 2007: 35-36) .

Table 1: Contents of "Morals" in junior high school

	Major value	1st yr (7th grade)	2nd yr (8th grade)	3rd yr (9th grade)
Personal life	-Life respect -Faithfulness -Honesty -Self-reliance -Self-control	-Meaning of life and morals -Personality -Human life -Adolescence		-Life plan and pursuit of value -Human life and value conflict -Moral problems and moral judgment
Family, neighbor and school	-Love and respect -Filial duty -Manners -Cooperation -School spirit	-Happy family life -Manners among relatives -Neighborhood manners -School manners		-Future exploration -Family, relatives, neighbors and moral problems -School life and moral problems
Social life	-Law-abiding -Consideration of others -Protection of environment -Justice -Community spirit		-Modern society and traditional morals -Modern society and the morality of citizenship -Democratic life -Economic ethics	
Nation	-National love -National security -Peaceful reunification -Humanity		-National development and culture -The importance of nation -Proper attitude to love a nation -The reunification of North and South	

Table 2: Han's analysis (2007) on bioethical consideration in junior high school

Area	Category	Subject	1st (7th gr)	2nd (8th gr)	3rd (9th gr)
Ethics of life respect	Respect for human life	Precious human life	○	○	
		Suicide			
		Smoking, drinking, and drug abuse		○	○
	Life respect for other creature	Concern and love for animals and plants		○	
		Welfare of animals and plants	○	○	○
	Life respect for environment	Destruction of animal and plant habitat	○	○	○
		Emission of pollutants	○	○	
Biomedical ethics	Bioethics related with birth and death	Abortion		○	
		Test tube			
		Gene test			
		Criteria of death, brain death			○
		Human vegetable, life-support machine, euthanasia			○
	Treatment of disease	organ, tissue transplant			○
		Releasing patient medical records			
	Distribution of medical resources	Fair social distribution of medical resource			
Ethics of bio-technology	Recognition of cutting edge biotechnology	Human genome project			
		Stem cell cultivation, human embryo cloning			○
		Clone			○
		Genetically manufacture organism, genetically codified food		○	
	Recognition of problems in biotechnology research process	Experiments involving human subjects			○
		Validity of the process of bioethical research			○
		Critical attitude of bioethical research outcome			

Most major values except life respect and protection of environment are not concerned with bioethical issues.

Han (2007) more specifically analyze bioethical considerations categorized into ethics of life respect, biomedical ethics, and ethics of bio-Technology. According to her analysis, Korean textbooks in junior high schools fail to provide constructive and balanced education. For the first and the second graders, moral textbooks hardly mention either biomedical ethics or biotech ethics(Table 2). They also address bioethical issues only as additional contents. Furthermore, by emphasizing on furnishing information to students, it is hard to encourage students' operant participation.

2) Senior high school

Like Morals in junior high school, "Life and Ethics" deals with bioethical issues in senior high school. According to Table 3, two areas such as "Life, sex and family Ethics" and "Scientific technology, environment, and information ethics" are most directly related with bioethics education among others (Lee, 2013: 29).

The emphasis on "ethics of life respect" is also noticeable in senior high school education as of 65% in total, compared with biomedical ethics (20%) and ethics of biotechnology (15%) (Lee, 2013: 52). Lee (2013) more specifically analyzes the frequency of subject mentioned in the textbook (Table 4):

Table 3: Contents of "Life and Ethics" in senior high school

Area	Subject
Modern life and applied ethics	Modern life and applied ethics Inquiry and practice of ethical problems Diverse approaches of ethical problems
Life, sex, and family ethics	Ethics of life and death Life science and ethics Ethics of sex and love Ethics in family relation Ethics among friends and neighbors
Scientific technology, environment, and information ethics	Scientific technology and ethics The relation between man and nature Ethical consideration on environmental problems Informational society and ethics
Social ethics and occupational ethics	Social morality and ethics Social justice and a just society Respect of human right and a fair society Importance of occupation and moral responsibility of occupational life
Culture and ethics	Aesthetic value vs. ethical value Religion and ethics Ethical problems and the necessities of life Ethics in multicultural society
Peace and ethics	Ethical issues of national reunification Ethical issues of global village

Table 4: Lee's analysis (2013) on bioethical consideration in senior high school

Area	Category	Subject	*f*
Ethics of life respect	Respect for human life	School violence	0
		Sexual violence	3
		Suicide	0
		Human dignity	0
		Death penalty system	2
		Respect one's own body	1
		Recognition of scientific technology, scientists' social responsibility	6
	Life respect for other creature	Protection of animals and plants, animal welfare	1
	Life respect for environment	Ethical consciousness and attitude towards nature	13
Biomedical ethics	Birth and death, sex determination	Test tube baby	0
		Surrogate mother	0
		Gene test	0
		Abortion	1
		Criteria of death, brain death	2
		Human vegetable, life-support machine, euthanasia	2
	Treatment of disease	Releasing patient medical records	0
		Organ, tissue transplant	2
		Patients' right to know	0
		Fair social distribution of medical resource	1
Ethics of biotechnology	Recognition of cutting edge biotechnology	Biological cloning, human cloning	2
		Stem cell cultivation, human embryo cloning	1
		Human genome project	0
		Genetically manufacture organism, genetically codified food	1
	Recognition of problems in biotechnology research process	Experiments involving human subjects	2

Table 5: Bioethics education at Gangnueng-Wonju National University and Daegu University

Area	Category	GWNU	Daegu University
Introduction	Basic theories	What is bioethics?	Definitions of bioethics
		Bioethics and theories of ethics	Principles of bioethics
Ethics of life respect	Respect for human life		Suicide
	Life respect for other creatures		
	Life respect for environment		Eco life-style
Biomedical ethics	Birth and death, sex determination	Abortion	Abortion
		Gene therapy	
		Euthanasia	Euthanasia
		Brain death	
			Surrogate mother
			Prenatal diagnosis
			Trade of eggs and sperm
	Treatment of disease	Organ transplant	Organ transplant
			Patients' rights
Ethics of biotechnology	Recognition of cutting edge biotechnology	Reproduction, Life reproduction	Reproductive technology
		Human cloning	Human cloning
		Embryonic stem cell research	
		Stem cell research	
		Animal biotechnology	Animal experiment
		Agriculture biotechnology	
		Food biotechnology	Genetically modified organism
			Human genome project
	Recognition of problems in biotechnology research process		Experiment on a human body

Whereas "ethical consciousness and attitude towards nature" and "recognition of scientific technology and scientists' social responsibility" stand out, school violence, suicide and human dignity are not mentioned in the area of ethics of life respect, which raises issues of serious concern, considering that the suicide rate among adolescents in Korea has increased dramatically for the past 10 years; in the area of biomedical ethics, "criteria of death and brain death", "human vegetable, life-support machine and euthanasia", and "organ and tissue transplant" are addressed twice respectively; and in the area of ethics of biotechnology, "biological cloning and human cloning" and "experiments involving human subjects" are also equally referred twice.

3. Bioethics education at university

Curriculum of bioethics education at the university level varies depending of lecturer's purpose of course. This study compares two cases, Gangnueong-Wonju National University and Daugu University. Whereas the former has offered Bioethics as a selective course since 2007, the latter first provided Bioethics in the Age of Human Cloning in 2004, the title of which has been changed into Bioethics and the Movie since 2006.

In spite of some differences between the two, Table 5 vividly presents that bioethical education at the university level tends to stress "biomedical ethics" and "ethics of biotechnology" rather than "ethics of life respect", when contents of lecture are reorganized based on three major areas. Considering that "ethics of life respect" is heavily emphasized in high school education, the shift toward the other two at university seems to provide a balanced perspective. As Yang and Koo (2009) claim, however, Bioethics education needs to be a compulsory course rather than a selective one. Yoo and Park's study (2010) also supports the importance of bioethics education at the university level by proving that the effects of a nursing ethics education on bioethics awareness were statistically significant.

4. Discussion

Concerns on bioethics were introduced in 1992 for the 6th Curricula of Junior and Senior High Schools in Korea. However, it is criticized that contents of bioethics education are insufficient not only quantitatively, but also qualitatively. According to Kim (2006: 61)'s analysis, only 5 out of 100 subjects are related with bioethics in the 7th grade Curriculum. Moreover, controversial issues are not directly addressed. For example, only illegal abortion based on ascertaining the gender of fetus is mentioned, without discussing the moral status of the embryo (Kim, 2006: 61). Considering all the details, it is hard to evaluate the current status of the bioethics education system highly.

For bioethics education at university, bioethics should be a compulsory course rather than a selective one and it is necessary to develop diverse educational supplements to help students have a great curiosity (Yang and Koo, 2009). The UNESCO Bioethics Core

Curriculum which aims to introduce the bioethical principles of *the Universal Declaration on Bioethics and Human Rights* to university students can contribute to providing an objective guideline of bioethics education with various cases (UNESCO, 2008).

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