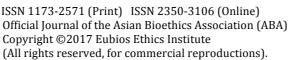
# Eubios Journal of Asian and International Bioethics



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### **Editorial: Ethical Therapy?**

Two of the ethical foundations of our life are loving life, and loving good or beneficence. The articles in this issue address therapy, trying to make the life of people better than they are because of a disease or condition. There are two papers on occupational therapy, which is an applied health science increasingly being discussed. Yamano looks at what type of clinical internship can be effective in Japan, and Sirianni and Wolbring present the results of a literature analysis. There is little mention of ethics in that literature to date, yet it clearly raises ethical issues. Surrogacy discussed by Kodama is in contrast a hot issue of bioethical reflection.

There are two descriptive bioethics papers, one from Nigeria and one from India, that help fill in some practical circumstances that we need to pay attention to. Practical ethics is required. This issue includes obituaries to two leading figures in Asian Bioethics. I hope that I do not need to write anymore this year. They both were active and supported EJAIB, and Jayapaul Azariah was a founding associate editor of the EJAIB - so after three decades he will be sorely In this issue I announce the missed. appointment of Prof. Nader Ghotbi as associate editor who has offered to help, and thank Prof. Masahiro Morioka who served as associate editor for 3 decades also. He joins the other members of the editorial board. - Darryl Macer

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Editorial address, and all correspondence to:

Prof. Darryl Macer, Ph.D., Hon.D.

President, American University of Sovereign Nations (AUSN), Arizona, USA

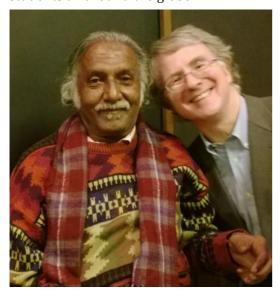
Email: darryl@eubios.info http://www.eubios.info
Registered address of EJAIB: P.O. Box 16 329, Hornby,
Christchurch 8441, New Zealand (Do not post items here;
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### Obituary to a dear friend, Professor Dr. Jayapaul Azariah (1939-2017)

- Darryl Macer, Ph.D., Hon.D.
President, American University of Sovereign Nations
Secretary, Asian Bioethics Association
Director, Eubios Ethics Institute

I am so sad to hear of the passing of my dear friend, colleague, partner in Indian and Asian Bioethics development, and teacher, Professor Dr. Jayapaul Azariah.

He is survived by his loving daughters, and family, and many dear friends, colleagues and students all around the globe.



Jay wrote many papers and books on zoology, ecology and bioethics. We were inseparable friends since we met in 1992 in Chennai (Madras as it was called in those days), intensely discussing bioethics and together we worked to develop bioethics in the 1990s. Twenty-five years later the term bioethics is widely known; many of our students are professors themselves developing a global understanding of bioethics. Bioethics is widely known in India and other countries in Asia, thanks to him.

Jay also served on the Board of Directors of the International Association of Bioethics, on the Bioethics Commission of the International Union of Biological Sciences (IUBS), and numerous other bodies. In 1998 he was the founding President of the All India Bioethics Association (AIBA). We shared the common understanding that love was the critical message of bioethics, hence the abbreviation "Ai" Bioethics Association, with reference to the Japanese (also the Chinese) word for love. He was dedicated to cross cultural understanding and exploration of bioethics,

through his deep Christian faith. He was devoted to Christian service as well as academic life.

Jay was the first Vice-President for India of the Asian Bioethics Association, and served also as President of Asian Bioethics Association. He was former Professor of Zoology and Former Dean of Life Sciences, University of Madras, though he had to follow the mandatory retirement at age 60 years, from hence he taught at many institutions in India. Jay passed away while also serving as Visiting Professor of Zoology and Bioethics (American University of Sovereign Nations); Visiting Professor of Kumamoto University, Japan; and Founding Associate Editor of Eubios Journal of Asian and International Bioethics (EJAIB).

Through some joint publications, joint research work since 1993, and spreading bioethics in India, Japan, Israel, Korea, Turkey, Indonesia, China and many other countries, there is a deeper understanding of bioethics. In the joint book, Bioethics in India, in 1998, we published one hundred scholars' papers on bioethics across India. There are numerous papers of his on the Eubios Ethics Institute website (<a href="https://www.eubios.info">www.eubios.info</a>).

Jay, your smile, love, loyalty, support, wisdom and intellect will be sadly missed. May you be together with dear Hilda, with so much work accomplished towards making our world a more ecologically and ethical one. I will remember Jay with his favourite sweater and smile.



There are also several youtube videos of his bioethics lectures on:

https://www.youtube.com/watch?v=KvxDyY-Obo0 (2003, TRT8, Eighth Tsukuba International Bioethics Roundtable, Japan)

https://www.youtube.com/watch?v=S6LA-\_u9iNY (2005 BBRT1, UNESCO Bangkok)

https://www.youtube.com/watch?v=jDYM-V6S7ZE&t=3s

(2007 ABC8, Bangkok)

https://www.youtube.com/watch?v=Xggih-rhfTc (2007 ABC8, Bangkok)

https://www.youtube.com/watch?v=x2qJQySZxBA &t=195s

(2009 ABC9, Indonesia, includes Prof. Azariah and Prof. Umar Jenie, who also passed away in 2017)

### Obituary to Professor Dr. Jayapaul Azariah (1939-2017)

- Irina Pollard, Ph.D.

Department of Biological Sciences, Faculty of Science and Engineering, Macquarie University, N.S.W. Australia, 2109

Email: irina.pollard@mq.edu.au

I feel a need to express my deep sadness at the passing of a close friend Dr. Jayapaul Azariah – a precious friendship that reached back over several decades. Our first social contacts took place at ABA's annual meetings during the early 1990s but soon expanded over a range of other enjoyable events – so friendship was regularly renewed during subsequent meetings and as an invited colleague at Biological Sciences, Madras University.

Being with Jay meant sharing a variety of activities that include literature, science, philosophy, bioethics, politics, religion as well as enjoyable gastronomic life experiences. Writing this has brought a strong characteristic memory that took place at a prestigious meeting in Paris where the projector would not work, but knowingly of my discomfort, Jay materialized from the audience and with one powerful knock my problem was resolved (I now exclusively use power point!)

Jay, I miss your humanity, ethical insights, positivity and friendship.



### The world has lost a Bridge between Bioethics and our Future Prof. Dr. Umar Anggara Jenie, Apt, Msc (22 August 1950 – 26 January 2017)

- Darryl Macer, Ph.D., Hon.D.
President, American University of Sovereign Nations (AUSN), USA
Secretary, Asian Bioethics Association
Former UNESCO Regional Adviser for Asia and the Pacific

The world has lost a leading scientist and bioethicist, and I have lost a teacher and friend. Professor Umar as he was fondly known to thousands of scholars around the world, was the public face of bioethics from Indonesia. Umar and his wisdom, inquiring mind, love and mediation, will be deeply missed by his colleagues around the world in many disciplines.

In his position as Chairman of the Indonesian Institute of Sciences (LIPI), founding Chairman of the Indonesian National Commission on Bioethics, and also as Vice-President for South-East Asia, and Vice-President for Indonesia, of the Asian Bioethics Association, Professor Jenie acted as a central bridge between development of research policy and practice for the development of bioethics through Asia and as an interface between Asia and the Global Community. For a decade he was the interface of Indonesia and Asian Bioethics, also chairing the Annual Meetings of the Asian Bioethics Association in Indonesia in 2008 and 2016. He attended the annual meetings all around the world inspiring his colleagues from different countries to work together, and to conduct research of glocal (global and local) relevance. In discussion of international policy, we have to articulate and rediscover values of Indonesia to take a leading role in a moderate approach to building a global order that is fair to all countries, not one dominated by the former colonial powers and the rich countries. he believed. Umar always supported and mentored young scholars to look to themselves and their culture to find solutions that are enduring and equitable.

Umar also served as a bridge between the natural science and social science fields that is critical for sound policy making in the emerging use of science and technology. Several of his informative talks are available for all to learn from on youtube; he also, an provided his time freely for public service as AUSN Visiting Professor in Medicinal Chemistry and Bioethics. Experts,

students and the public could all learn from him how to share wisdom from diverse fields of genomics, medicinal chemistry, history, philosophy, and cross cultural communication and policy making.

Prof. Jenie's service to UNESCO as a member of Intergovernmental Committee UNESCO's Bioethics, as well as in numerous roles as an international expert on science, was instrumental to the implementation of the Universal Declaration on the Human Genome and Human Rights, into laws in Indonesia, ASEAN and globally. As former UNESCO Regional Adviser to Asia and the Pacific, and the former and founding member of UNESCO's International Bioethics Committee from New Zealand, I had the pleasure to work with Umar on the translation of mere words of governments and the United Nations into practices that save the lives of vulnerable people, and protect our biodiversity and biosphere. Future generations will appreciate the foresight of policies that he helped formulate. He not only fought to protect people, but also animals and plants that our world is blessed with. Umar served us all, and the world was blessed to have him with us for 67 years - still too short for his friends and colleagues. God has blessed us to have Umar among us, and may you rest in peace sure that your wisdom will continue to inspire others.



Jogyakarta 2008



Beppu, Japan, 2015

### Risks Present in the Cambodian Surrogacy Business

-Masayuki Kodama, Ph.D.

Professor Emeritus at National Institute of Fitness and Sports in Kanoya, Japan; 13-237-6 Honmachi, Higashiyama-ku, Kyoto City, Japan, 605-0981 Email: kodama@nifs-k.ac.jp

#### **Abstract**

The Thai temporary National Assembly passed the Protection for Children Born through Assisted Reproductive Technologies Act, 2015 on February 19, 2015. The passing of Thailand's law regulating reproductive medicine (surrogacy) was followed by an enactment with the approval of the cabinet and King Bhumibol Adulyadej in July 2015. Since then, some surrogacy mediation agencies based in Thailand, including Japanese surrogacy agencies, have shifted their attention from Thailand to other Asian countries, such as Cambodia, Georgia and others. This paper discusses the background of the rapid growth of the Cambodian surrogacy industry as well as the government's announcement of a complete ban on commercial surrogacy, and also the risks inherent in Cambodian surrogacy business. This paper aims to provide related information to Japanese surrogacy patients and researchers in reproductive medicine.

### 1. Introduction

The New Life Global Network (NLGN) has been in the midst of international expansion since the passage of Thailand's *Protection for Children Born* through Assisted Reproductive Technologies Act (W.S.U.

คุ้มครองเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ท างการแพทย์ พ.ศ. 2558) on July 30, 2015 through the time of this writing (January 2017). Led by Mariam Kukunashvili (MD, PhD), the organization has spread its operations from Thailand, where it established its initial foothold, to the neighboring countries of Cambodia, Laos, and Myanmar.<sup>1</sup>

Following being shut out of Thailand in 2015 due to national law, the first alternative host country to which NLGN expanded its operations was Cambodia, which lacked laws concerning reproductive medicine, in particular assisted

<sup>&</sup>lt;sup>1</sup> NLGN is a commercial organization that handles egg provision and surrogacy services. Headquartered in Georgia, this intermediary agency for reproductive medicine services also has offices in India, South Africa, Poland, Armenia, and Ukraine, Mexico, Kenya, and Southeast Asia, and claims on its website to have helped over 7000 couples and individuals to build their families. (https://www.newlifeasia.net/)

reproductive medicine (ART) or surrogacy. Already facing "more than 50 surrogacy brokers... advertising online for services in Cambodia" as of August  $2016^{\ 2}$ , the Cambodian government announced a complete ban on commercial surrogacy in November  $2016.^3$ 

Despite the proclamation, neither NLGN nor Japanese surrogacy brokers have suspended business operations in Cambodia as of the time of this writing (January 2017), instead waiting to see the government's next moves. Such businesses targeted by the complete ban on commercial surrogacy can still be easily accessed, but clients risk paying an extremely high price for contracting their services. To what risks are surrogacy patients exposed as a result of the business priorities of Cambodian surrogacy agencies? This manuscript aims to identify the risks inherent in surrogacy businesses that have spread from Thailand to other neighboring nations.

# 2. The Rapid Growth of the Cambodian Surrogacy Industry, and the Government's Announcement of a Complete Ban on Commercial Surrogacy

Thailand's interim legislature passed the *Protection* for Children Born through Assisted Reproductive Technologies Act, 2015 on February 19, 2015. It was soon followed by the Nepalese government, which took the step of completely banning commercial surrogacy in the country in September 2015. Some surrogacy mediation agencies responded to these moves by considering alternative host countries to Thailand for surrogacy operations: one of these is neighboring Cambodia, which permits surrogacy treatment and lacks legislation regarding surrogacy and other forms of reproductive medicine (for example, the reproductive medicine agency NLGN, headquartered in Georgia and operating in Thailand, opened a Cambodian branch in March 2015). Following Dr. Sean Sokteang's opening of the country's first IVF clinic, Fertility Clinic of Cambodia, in September 2014, the country has experienced rapid growth in the field of reproductive medicine, and now has 16 surrogacy clinics. Concerned about the physical and mental health of Cambodian surrogate mothers and surrogate children, the Cambodian government announced a ban on surrogacy in November 2014, but the activities of surrogacy brokers have continued unabated.

addition. the Indian government's announcement of measures to completely ban commercial surrogacy drove an exodus of gay couples to Thailand in 2013. This triggered the interim military junta of Prayuth Chan-ocha to implement the *Protection for Children Born Through* Assisted Reproductive Technologies Act, 2015, whereupon the preferred destinations of gay surrogacy tourists changed to Nepal and the Mexican state of Tabasco. The authorities were bewildered by the legions of gay couples, driven out of country after country in their search for international surrogacy, and by the end of 2015 both Nepal and Mexico had adopted measures to ban commercial surrogacy by the end of 2015, ultimately leading these groups to Cambodia.

Two major home countries from which gay surrogacy tourists have flocked to Thailand since 2013 are Australia<sup>4</sup> and Israel<sup>5</sup>. In Australia, neither surrogacy nor adoption for gay couples is recognized. According to the Australian Department of Foreign Affairs and documentation 6, 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. Even if they wanted

<sup>&</sup>lt;sup>2</sup> As Surrogacy Trade Grows, Government Charts Course (*The Cambodia Daily*, August 27, 2016).

<sup>&</sup>lt;sup>3</sup> Cambodia bans commercial surrogacy by Xavier Symons [BioEdge, 5 Nov 2016].

<sup>&</sup>lt;sup>4</sup> Commercial surrogacy is banned in Australia, but altruistic surrogacy is permitted for both opposite-sex and same-sex couples. Passed in Tasmania in 2012, *Surrogacy Act No. 34* and *Surrogacy (Consequential Amendments) Act No. 31* permit same-sex couples to have surrogate children as well as opposite-sex couples. Tasmania passes gay, de facto surrogacy bill (*ABC NEWS*, August 30, 2012).

<sup>&</sup>lt;sup>5</sup> While compensated surrogacy has been legal in Israel following the 1996 enactment of the Embryo Carrying Agreements Law, applicants are restricted to opposite-sex couples. Moreover, religious law permits surrogacy only when the commissioning mother and father (whether married or not) as well as the surrogate mother are Jewish (80% of the Israeli population is Jewish). Israel lacks civil marriage: only religious marriage exists, which is ordained by rabbis based on religious law. As a result, there are many de facto married couples in the country who are not legally married. In January 2014, Israel's High Court of Justice recognized a gay couple's adoption of a surrogate child genetically related to one of the parents (High Court orders Israel to recognize gay adoption of child born through surrogacy; The Jerusalem Post, January 28, 2014). However, a 2014 amendment bill to the Embryo Carrying Agreements Law, intended to extend the ability to commission commercial surrogacy to same-sex and de facto married couples and single men and women, failed to pass.

<sup>&</sup>lt;sup>6</sup> More parents defy law with overseas surrogacy (*The Sydney Morning Herald*, September 14, 2013)

to, gay couples from Australia and Israel could not change course and commission surrogacy in Georgia (the location of NLGN headquarters), because Georgian law restricts those who can commission surrogacy to married heterosexual couples; instead, they headed to Thailand's neighboring country of Cambodia.

Flooded with the influx of gay couples, the Cambodian government gave notice of a coming crackdown on commercial surrogacy in a November 11, 2015 article in the *Khmer Times*<sup>7</sup>, warning that "Government officials plan to classify surrogacy as a form of human trafficking".<sup>8</sup> Despite the announcement, the number of surrogacy brokers working clandestinely in Cambodia continued to increase. Concerned about the massive influx of not only opposite-sex couples, but also same-sex couples and single persons from foreign countries seeking surrogacy, the U.N. Population Fund's representative to Cambodia warned in August 2016:

"There is currently no legal framework regulating surrogacy in Cambodia, even though more than 50 surrogacy brokers are advertising online for services in Cambodia, and Australian couples are traveling here seeking surrogate services. They need at least a legal framework to avoid malpractices. In the absence of a legal framework, there is much more risk of having abuse and malpractice."9

In September 2016, the Ministry of Women's Affairs in Cambodia held a conference about the effects of unregulated surrogacy, and announced it would take measure to protect the human rights of Cambodian women and children. On November 3, 2016, the Cambodian government subsequently notified all medical institutions in Phnom Penh of an impending complete ban on commercial surrogacy.

Despite this threat, NLGN claims that there are no laws related to ART or surrogacy regulations in Cambodia, and therefore surrogacy is not illegal in the country. Based on this determination, NLGN continues to recruit and manage surrogate mothers in Thailand and Cambodia, and to act as a mediator between Cambodian clinics and medical refugees

from around the world. At the same time as it pays off authorities to defend itself from repeated investigations by the Cambodian socialist administration, NLGN is fostering new surrogacy markets in the cities of Vientiane (Laos) and Naypyidaw (Myanmar) as a back-up plan for its surrogacy program.

Despite their opaque future, parties seeking surrogacy are directed to these Cambodian surrogacy clinics by advertisements posted on the websites of some Japanese surrogacy agencies (Company A and Company B). NLGN transfers embryos fertilized via IVF and frozen in Thailand to Cambodian clinics, where they are implanted in Thai and Cambodian surrogate mothers. 10 The Japanese surrogacy agencies work in a similar way: e.g. Company A inspects chromosomes from frozen embryos prepared in Japan at a partner Thai clinic using a next-generation sequencer (NGS). 11 Only the healthy frozen embryos that pass inspection are then brought to a partner clinic in Cambodia by a Japanese surrogacy agent, where a local doctor implants them into surrogate mothers.

What are the risks to the patients of possible suffering due to the business priorities and attitudes of Cambodian surrogacy agents?

### 3. Risks Inherent in the Cambodian Surrogacy Business

While both Thailand and Cambodia are Theravada Buddhist countries, there are striking differences in their attitudes towards the surrogacy industry. In contrast to Thailand, where there is a strong tendency to view surrogacy as thamboon (ทำบณ) or 'a pious act' for extending a helping hand to people with reproductive disabilities, this way of thinking is rare in Cambodia. As a result, a married woman delivering a child belonging to someone other than her spouse appears quite abnormal to the average Cambodian. The national sentiment to stop the surrogacy industry as a form of prostitution or child trafficking (i.e. in violation of Article 332 of the Penal Code: Intermediary between an Adoptive Parent and a Pregnant Woman referring to "Ban on Human Trafficking") has made searching for

<sup>&</sup>lt;sup>7</sup> Gov't to Crack Down on Surrogacy Clinics (*Khmer Times*, November 11, 2015)

<sup>&</sup>lt;sup>8</sup> The legal basis for this crackdown is Cambodian domestic law: specifically Article 332 of the Penal Code: *Intermediary between an Adoptive Parent and a Pregnant Woman* referring to "Ban on Human Trafficking". In addition, Cambodia is party to the UN's *Trafficking Protocol*, written in November 2000 to supplement the *Convention against Transnational Organized Crime*. However, the reality remains that impoverished Cambodian women and children still become victims of human trafficking.

<sup>&</sup>lt;sup>9</sup> As Surrogacy Trade Grows, Government Charts Course (*The Cambodia Daily*, August 27, 2016)

<sup>&</sup>lt;sup>10</sup> Some companies specialize in the transport of biological materials. For example, Cryoport, Inc. has recently expanded its business to not only the Czech Republic, a country with many egg donors, but also Cambodia, hailed as an alternative to Thailand for surrogacy tourists. The company uses specialized "cold chain" technology, a low-temperature distribution system for transporting gametes and fertilized eggs, whereby cells cryogenically frozen at −151 °C and a calcium silicate sponge soaked in liquid nitrogen are placed in a Dewar flask and transported to the destination.

<sup>&</sup>lt;sup>1</sup> The Japan Society of Obstetrics and Gynecology does not permit pre-implantation genetic screening (PGS) or whole-chromosome NGS.

surrogate mothers a more difficult task for brokers than in Thailand. Accordingly, the majority of women who undertake surrogate motherhood in Cambodian society are inevitably divorced women in financial distress or poor foreign women from neighboring countries.

Moreover, Cambodian law regards the woman who gives birth to a child as its legal mother. This means that when a surrogate mother gives birth to the child of a commissioning couple, she is recognized as the child's legal mother simply by lending her uterus, even if she lacks a genetic relationship with the child. This legal situation means that commissioning couples from Japan must jump over several hurdles in order to bring home a surrogate child genetically related to them but born in Cambodia between a Japanese father and a Cambodian surrogate mother. First, the surrogate mother must undergo legal proceedings to relinquish her parental rights; second, the child must be recorded in the couple's family registry, and obtain Japanese citizenship; and third, the child must be issued both a passport by the Japanese government and an exit visa by the Cambodian government. Are these expectations realistic?

Because of its November 3, 2016 announcement of a complete ban on commercial surrogacy to all medical institutions in Phnom Penh, the Cambodian government is unlikely to be able to publicly issue exit visas to surrogate children born in violation of it.<sup>12</sup> More importantly, Japan lacks legislation regarding reproductive medicine, particularly surrogacy; therefore, the Embassy of Japan in Cambodia cannot issue a Japanese passport to a surrogate child born in Cambodia if it is to respect the official governmental positions of both countries. 13 The legalization of an international adoption system in Cambodia notwithstanding, the announcement of a complete ban on commercial surrogacy makes it impossible not only for the Embassy of Japan in Cambodia to issue passports to surrogate children born in Cambodia, but also for the Cambodian government to grant exit visas to such children, since there is no legal system for transferring the surrogate child to a commissioning couple at present. In short, it will likely become impossible for a surrogate child to be transferred to a commissioning couple.

However, Cambodia is a country where one can purchase citizenship. Aware of the culture of "legal flexibility" in the country, surrogacy brokers have traditionally been able to resolve most issues by bribing authorities in secret. If citizenship can be purchased, certainly there is a chance that exit visas can be bought as well. A broker can bribe relevant Cambodian hospital officials to omit the surrogate mother's name from the "Mother" field of a surrogate child's birth certificate, thereby avoiding any trouble when the commissioning couple registers its birth at their city office upon returning to Japan. This workaround is made possible by a Ministry of Justice directive issued in 1961, which notes no special scrutiny for screening married couples upon their return home with a newborn child, assuming the women commissioning surrogacy is under 50 years old.<sup>14</sup>

The hard reality is that bribery is widely tolerated in Cambodia, as it is in many poor socialist countries. This fact and the loophole above notwithstanding, voices such as the Ministry of Women's Affairs are loudly calling for the protection of the human rights of women and children. Combined with the recent notification to ban commercial surrogacy, this trend suggests that the influence of bribery, traditionally effective in ages past, may lose some of its potency. In other words, the November 3, 2016 notification must be taken as a sign that with Cambodian medical institutions waiting for the government's next moves, the ability of surrogate children born there to emigrate the country is in jeopardy.

### 4. Conclusion

Despite this, some surrogacy agencies in Japan have yet to withdraw their Cambodian surrogacy recruitment advertisements from their website as of the time of this writing (January 2017). Why is this?

On their websites, Company A and Company B claim to "perform surrogacy in Cambodia", lay out the timeline of each Cambodian surrogacy program, and state that "the child is transferred to the married couple immediately upon delivery."

However, even as the Cambodia government makes explicit its policies to ban commercial

<sup>&</sup>lt;sup>12</sup> Immediately after the distribution of the *Notification of a Complete Ban on Commercial Surrogacy* on November 3, 2016, anti-human-trafficking police in Phnom Penh arrested three surrogacy providers (Tammy Davis-Charles, the Australian founder of a surrogacy agency, and two Cambodians) on suspicion of violation of Penal Code Article 332: *Intermediary between an Adoptive Parent and a Pregnant Woman* referring to "Ban on Human Trafficking". (Surrogacy in Cambodia Faces First Official Charges, accessed November 22, 2016 at: http://www.sensiblesurrogacy.com/ surrogacy-in-cambodia-comesto-end-amidst-arrests/)

<sup>&</sup>lt;sup>13</sup> A surrogate child could potentially be granted Japanese citizenship and a passport through extra-legal measures, if the genetic relatedness of the child and its Japanese parent(s) (i.e., the commissioning couple) could be certified via DNA screening.

<sup>&</sup>lt;sup>14</sup> "[Authorities must] Check the facts of the birth when the mother is 50 years or older." (Ministry of Justice directive, 1961)

surrogacy, the above-mentioned surrogacy agencies have maintained a uniform silence concerning the expected risks facing the return of the surrogate child to Japan. As of January 2017, Cambodia as a surrogacy destination exposes surrogate children born there to inherent risks. There is only one word for the behavior of these Japanese surrogacy agencies which send surrogacy-seeking couples to Cambodia while feigning ignorance of the risks involved: dishonest.

Note: This paper is based on a paper presented at the Tenth Kumamoto University International Bioethics Roundtable, November 2016.

Consideration of Appropriate Clinical Internships for Occupational Therapy Students in Japan

- Katsuaki Yamano, Ph.D., OTR Department of Rehabilitation, Faculty of Health Science, Kumamoto Health Science University Email: yamano@kumamoto-hsu.ac.jp

### 1. Introduction

The purpose of this study was to determine the appropriate clinical internship for occupational therapy students by comparing two different styles: "in charge of client style and clinical clerkship".

All occupational therapy students in Japan must practice clinical internship for more than 1000 hours in order to qualify for the national exam for occupational therapists. Since 1965, a physical and occupational therapist law has been established in Japan stipulating that students practice an internship where they are in charge of clients and write case reports under a supervisor's guidance. However, a number of occupational therapists have been practicing clinical clerkship from the 2000s onward.

In the clinical education for occupational therapy students, it is important to compare in charge of client style with the clinical clerkship style and to consider which of these two styles of clinical internship appropriately.

### 2. Occupational therapy process in Japan

Occupational therapists in Japan need prescriptions from a physician to practice therapy in order to have compliance with the law. Once they have prescriptions, occupational therapists complete the following steps: 1. Evaluate the clients using a variety of methods. 2. Determine the state of functioning and the real problem. 3. Plan an occupational therapy intervention, set long-term and short-term goals, and select and establish the course for occupational therapy. 4. Practice occupational therapy. Most of the therapy sessions range from 20 minutes to an hour. 5. Therapists routinely reevaluate the client (Table1).

Occupational therapists assess the effect of therapy by comparing previous and current evaluation data results. If the client completes the goal, it may be the end of therapy depending on the assessment by the physician. If not, therapists repeat the process by practicing steps 1 to 5 again.

**Table 1**: Occupational Therapy Process in Japan

- 0. Prescription by physician
- 1. Evaluation: interview, observation, collecting information, and measurement for clients
- 2. Problem definition: International Classification of Functioning (ICF) is used to assess the results of evaluation and define problems that are to be targeted through occupational therapy interventions
- 3. Intervention planning: goal (long or short-term) setting; select and establish the course of therapy.
- 4. Intervention implementation: verification of the effects every therapy
- 5. Re-evaluation: systematically re-collect initial evaluation data and compare evaluation and re-evaluation data to determine if outcomes have been met and if discontinuation is appropriate; if not, determine subsequent action.
- 6. Completion

## 3. Legal regulations for clinical internship in occupational therapy in Japan

The rules for educational facilities of physical and occupational therapists (universities and vocational colleges offering a major in physical and occupational therapy) are outlined in Article3-2, notified by the Ministry of Education, Culture, Sports, Science and Technology and by the Ministry of Health, Labour and Welfare and stipulate that physical and occupational therapy students must practice a clinical internship of more than 25 credits (810 hours: 45 hours per credit) and complete more than two-thirds of the credits in a medical setting (the Ministry of Education, Culture, Sports, Science and Technology and The Ministry of Health, Labour and Welfare, 1966).

Besides. the Japanese Association of Occupational therapists (JAOT) requires internship of more than 1000 hours including internships of more than six consecutive weeks (Japanese Association of Occupational Therapists, 2014). This criterion is based on the international educational standards of the World Federation of Occupational Therapists (WFOT). Specifically, it is necessary to meet these criteria in order to attain the standard, which is necessary if Japanese occupational therapists desire to work or study abroad (Hockinget al. 2002, p.1).

The guide for teaching physical and occupational therapy at training institutions as stated by the Ministry of Health, Labour and Welfare lists the following four points as qualifications for the supervisor and the facility of the practice of occupational therapy internship:

1) An experienced occupational therapist (clinical experience of over 3 years since licensure) supervises the student. 2) It is desirable that the facility is located near the training school. 3) It is desirable that the proportion of students to supervisor is approximately 2:1. 4) The facility must have adequate equipment to practice the internship (the Ministry of Health, Labour and Welfare, 1999).

## 4. The significance and purpose of clinical internship for occupational therapy students

The Japanese Association of Occupational Therapists (JAOT) published the fourth edition of its guidelines for the occupational therapy clinical internship in 2010. JAOT has defined the significance and purpose of a clinical internship in the guidelines (Japanese Association of Occupational Therapists, 2010).

According to the JAOT, the significance of a clinical internship is that occupational therapy students experience occupational therapy practice in the facility and learn the appropriate knowledge, technology, skills, and attitude in the training course. The purpose of a clinical internship is for occupational therapy students to develop an understanding of the perspective of the client, as well as the knowledge, technology, skills, and attitude of a therapist through occupational therapy planning and treatment, and offer guidance and support to clients under the supervisor's guidance, which will improve their understanding as a healthcare professional (Japanese Association of Occupational Therapists, 2010, p.10).

### 5. Charge of client style internship for occupational therapy students in Japan

In the charge of client style internship, occupational therapy students practice client-based occupational therapy and write case reports under a supervisor's guidance.

The JAOT defines the goals of the clinical internship as follows: "occupational therapy students are able to practice occupational therapy for general clients under the supervisor's guidance, and act as a therapist professionally" (Japanese Association of Occupational Therapists, 2010, p.17). In other words, the JAOT recommends an internship congruent with the charge of client style.

The strength of the charge of client style internship is that students are able to repeatedly experience the occupational therapy process, and to develop the skills of clinical reasoning through a relationship with the client. Additionally, the supervisor can allocate time for guidance, and, students are able to thoroughly study the client's clinical condition.

### 6. Criticisms of the charge of client style internship

The charge of client style has been practiced in many occupational therapy training settings in Japan since occupational therapy training courses began in 1963. There were few Japanese therapists with a license in those days. Therefore, it was necessary to train many therapists. The number of registered occupational therapists is insufficient in Japan today to meet the needs of an aging population. It could be argued that training more occupational therapists is one of the important strengths of the charge of client style.

However, some therapists have criticisms concerning the charge of client style internship. Sato, an occupational therapist, notes that the charge of client style internship has seven limitations. 1. Insufficient internship facilities. 2. Insufficient guidance times. 3. The student's "power of clinical reasoning" does not develop when writing case reports. 4. The main guidance of the supervisors is often restricted to the contents of case report because they cannot directly lead the student's practice. 5. The number of clients who do not consent to be treated by students has increased. 6. There is an increase in students' physical and mental fatigue in practicing the internship all day. 7. Supervisor's inability to lead (Sato, 2015, pp.6-9).

Nakagawa, a physical therapist, has also criticized the charge of client style internship for physical and occupational therapy students, making the following six points: 1. The supervisor cannot judge the student's development in the affective and psychomotor domains because it is dependent on the student's ability to write a case report. 2. The

student has to practice client therapy despite not possessing a license. 3. The student is only able to observe the cases of high-risk clients. Therefore, the student cannot experience the complete clinical reality. 4. Clients do not receive enough therapy, quantitatively and qualitatively, from students. 5. Supervisors have limited time for students, because the health service care fee for occupational therapy has slowly decreased, whereas the number of clients is increasing. 6. It is understandable that many clients do not consent to treatment by the student (Nakagawa, 2011a, pp.21-4).

Aida, an occupational therapist, argues that students with little clinical experience are too nervous and not skilled to practice, and cannot write case reports that meet supervisor's expectations (Aida, 2015).

### 7. Legal interpretation of the clinical internship in Japan

It is important to consider the criticism by Nakagawa that the student with no license practices therapy on clients in the course of the internship. Students who have no license to practice therapy are, in their clinical internships, in violation of physical therapist and occupational therapist law and of those pertaining to fee for healthcare services in Japan (Nakagawa, 2011b, pp.13-4).

The most important law for Japanese registered occupational therapists is the physical occupational therapist therapist and established in 1965. Article 2-4 states, "the term occupational therapist as used in this act means a person that is qualified with a license by the Ministry of Health, Labor, and Welfare, uses the style of 'Occupational Therapist', and practices in occupational therapy with a physician's prescription".

On the other hand, the ministry ordinance concerning fee for healthcare services in Japan establishes that "it is performed under the direct guidance of the physician, and the occupational therapy considers it as being performed under a physician or the monitoring of an occupational therapist".

One member of the Diet submitted a written inquiry in March of 2016 asking if it is violation of the law for non-licensed students to practice physical or occupational therapy in internships, and if hospitals and facilities receive a medical fee from treatment performed by students. The government answered that "these practices are not a problem based on the interpretation of the law, if a physician or experienced therapist always provides guidance, ensures client safety, and the client consents to

practice by a student, and it is also not a problem if adequate guidance is provided by a physician or experienced therapist based on the interpretation of the law." This is based on an interpretation of the Medical Practitioners Act by the Ministry of Health and Welfare in 1991 (Ministry of Health and Welfare, 1991).

### 8. Clinical clerkship style internship for occupational therapy students

As discussed in the preceding section, it is not against the law for a student with no license to practice therapy. However, it is doubtful whether the student's therapy is the most effective for the client as well as therapist (supervisor). Therefore, it is not surprising even if the client does not consent to receive therapy from a student. If so, it will not be possible for the student to practice internship. Thus, some therapists have emphasized on clinical clerkship style internship to manage this issue.

The clinical clerkship style internship in Japan has been practiced by physician since around 2004 (Japan Society for Medical Education, 2005, p.11). Its prevalence among physicians in Japan has been affected by the clinical training system, which has made it a legal obligation in 2004 (Japan Society for Medical Education, 2005, p.11).

According to the Japan Society for Medical Education, in the clinical clerkship style internship, medical students participate in medical examinations as a team member. They assist in the medical examination by engaging in a limited range of medical practices under a supervisory physician's guidance, and develop the knowledge, technology, skills, and attitude of a physician. They have responsibility for the patients because their practice is on the medical record (Japan Society for Medical Education, 2005, p.65).

The clinical clerkship style internship for physical and occupational therapy was also introduced around 2000 (Nakagawa & Kano, 2001). Nakagawa defines that in the clinical clerkship, the student participates in the rehabilitation team as an assistant, which facilitates the development of professional skills and attitudes and ethical reasoning (Nakagawa, 2011c, p.37).

There are three steps in the practice of the clinical clerkship style internship: 1. Observation: the student observes the supervisor's practice and receives explanations concerning therapy. 2. Imitation: the student practices therapy under the supervisor's guidance. 3. Practice: the student is able to explain risk factors to clients, and practices therapy individually as permitted by the supervisor (Nakagawa, 2011c, pp.38-9).

### 9. Strengths of the clinical clerkship style internship

Nakagawa introduces seven strengths of the clinical clerkship. 1. The students do not write the case report, which reduces their physical and mental exhaustion. 2. Supervisors are freed from checking the report, and are thus able to devote additional time to leading the students and practicing therapy. 3. The student interacts with the supervisor all day as an assistant, and is therefore always able to practice under supervision. 4. The student is able to experience various clinical situations, and learn suitable actions. 5. Supervisors are able to have a dialogue with students, and effectively guide them. 6. Supervisors are able to ensure adequate therapy time for the client as well as guidance for the student. 7. Clients are likely to consent to the student being a part of their treatment team (Nakagawa, 2011c, pp.37-41).

### 10. Criticisms of the clinical clerkship style internship

There are also some criticisms of the clinical clerkship style internship. Aida mentions that there are few educational facilities that recommend clinical clerkships, and many therapists do not have a good understanding of clinical clerkships (Aida, 2015).

Although Hanafusa (occupational therapist for physical dysfunction) and Uda (occupational therapist for psychiatric dysfunction) practice the three-step clinical clerkship, there are several points that differ because of the difference in clinical specialization. They demand that students produce a planning report and occupational therapy summary for the client and case conference material for the other team staff if necessary (Hanafusa 2016; Uda 2016).

### 11. Discussion

It can be a valuable experience for students to practice current occupational therapy processes through the charge of client style internship. However, this style may cause the students to use their energy unproductively in producing case reports. Most of the students are not skilled enough to practice occupational therapy with the little clinical experience they gain. For example, the supervisor's guidance time with the student is limited to the time allowed practicing therapy as set by the healthcare service fee (max 60 minutes). Therefore, they have minimal discussion with clients and therapists, resulting in insufficient time for guiding the students while providing therapy for many clients. In this situation, the students do not have adequate time to acquire the necessary skills as therapists and to write case reports during the clinical internship. As a result, students are not able to learn about the professional responsibilities of an occupational therapist.

In comparison, clinical internship enables students to enhance their professional qualities and provides the experience needed to gain the true meaning of the occupational therapy profession. Considering these viewpoints, the clinical clerkship is a better style of clinical internship than the charge of client style for occupational therapy students. However, the clinical clerkship style also has some problems. Some of the students are limited to observation or imitation in the internship. There are reasons for this: 1. Many of the occupational therapy students cannot act in the internship because they are not skilled enough. 2. The supervisor does not set internship planning and may not have a strategy for leading because of a lack of understanding of the clinical clerkship. 3. educational facility may not establish attainment goals for every step. The students may lose focus if their only purpose is to earn enough credits, and they cannot acquire occupational therapy clinical thinking skills if they do not write case reports. In other words, it is easy for the internship to become a mere label rather than a productive experience.

Supervisors need a better understanding of the clinical clerkship type of internship. Furthermore, lecturers in the occupational therapy training setting and supervisors need to cooperatively plan the clinical internship, and explain to students the purpose, passing level, and contents of the clinical clerkship style internship.

### 12. Conclusion

It is desirable that occupational therapy students practice more in the clinical clerkship style during the clinical internships. However, it is hard to say that supervisors have an adequate understanding of the needed clinical clerkship. There needs to be a supervisor instruction course concerning the clinical clerkship style in the future.

Note: This paper is based on a presentation at the Tenth Kumamoto University International Bioethics Roundtable, November 2016.

### References

Aida T. 2015. *Kurinikarukurakusippu ni motoduku rinsyoukyouiku toha* (What is clinical education based on clinical clerkship?). *JJOT* 49 (11): 1114-20.

Hanafusa K. 2016. rinshoujissyuusidousya no tachiba kara, shintaisyougai ryouiki (kyuuseiki) (From a point of view of a supervisor – specialized for physical

dysfunction (acute stage)). Japan Journal of Occupational Therapy 50 (1): 80-4.

Hocking C, Ness NE. 2002. World Federation of Occupational Therapists Revised Minimum Standards for the Education of Occupational Therapists 2002, The council of the World Federation of Occupational Therapists.

Japan Society for Medical Education. 2005. shinryousankagata rinnshoujissyu gaido (Guideline of clinical clerkship style internship), shinoharashuppansya.

Japanese Association of Occupational Therapists. 2010. Sagyoryoho rinshojissyu no tebiki dai4pan (The guideline of occupational therapy clinical internship, fourth edition). http://www.jaot.or.jp/wp-content/ uploads/2012/08/rinshoujisshuVer.422203251.pdf (Accessed on 2016.11.14)

Japanese Association of Occupational Therapists. 2014. sagyoryohoshi kyouiku no saitei kijun kaitei dai 3 pan (the minimum standard of education for occupational therapist). (Accessed on 2017.1.30) http://www.jaot.or.jp/wp-content/uploads/2013/ 12/OTmimimumstandard-3nd1.pdf>.

Ministry of Health and Welfare. 1991. Rinsyojissyu kenntou iinkai saisyu houkoku 2 (The Final Report by the committee on consideration of clinical internship (Accessed physician 2). on 2017.1.13) http://www.mext.go.jp/a\_menu/koutou/iryou/\_icsFil es/afieldfile/2013/03/13/1329799\_02.pdf >

Ministry of Health, Labour and Welfare. 1999. The guide to teaching for physical and occupational therapy institutions. (Accessed on training 2017.1.6) https://kouseikyoku.mhlw.go.jp/kantoshinetsu/shoka n/kankeihourei/documents/yoryo\_rigaku.pdf>

Ministry of Health, Labour and Welfare. 2016. Heisei 28 nendo sinryohosyukaitei ni tsuite, (The Guidance of the healthcare service fee in 2015-6) (Accessed on 2017.1.25)http://www.mhlw.go.jp/file.jsp?id=335763 &name=file/06-Seisakujouhou-12400000-

Hokenkyoku/ 0000114819.pdf>

Nakagawa N, Kano K. 2001. Evaluation Method on a Clinical Clerkship. Physical Therapy Japan 28 (4): 198-

Nakagawa N (a). 2011. rinshojissyu no kennsyo - kanja tanntosei jissyu no houkai (Inspection of clinical internship- collapse of the charge of client style). Nakagawa N (ed.) Serapisutokyouiku no tameno Kurinikarukurakusippu no susume (Recommendation of clinical clerkship for therapist education, second edition), Miwa-shoten, pp.20-5.

Nakagawa N (b). 2011. serapisuto kyoiku ni okeru rinshojissyu no kiki (a crisis of clinical internship in the education for physical and occupational therapists). Nakagawa N (ed.) Serapisutokyouiku no tameno Kurinikarukurakusippu no susume dai2han. (Recommendation of clinical clerkship for therapist education, second edition), Miwa-shoten, pp.12-9.

Nakagawa N (c). 2011. serapisuto kyoiku ni okeru kurinikaru kurakusippu no souzou (A Creation of clinical clerkship in the education for physical and occupational therapists). Nakagawa Serapisutokyouiku no tameno Kurinikarukurakusippu

no susume dai2han, (Recommendation of clinical clerkship for therapist education, second edition), Miwa-shoten, pp.37-42.

Rogers JC, Holm MB. 2009. Occupational Therapy Process. Crepeau EB, Cohn ES, schell BAB (eds.) Willard and Spackman's Occupational Therapy 11th edition, Lippincott Williams & Wilkins, p.480.

Sato A. 2015. Ima naze kurinikarukurakushippujissyu nanoka? (Why is clinical clerkship style internship now?) Aomori sagyoryoho kenkyu 24 (1): 5-15.

Uda H. 2016. Rinshojissyusidosya no tachiba kara, seishinsyogai ryoiki (from a point of view of a supervisor - specialized for psychiatric dysfunction). *JJOT* 50 (3): 272-8.

### Lack of ethical reasoning in the innovation narrative of **Occupational Therapy and Occupational Science literature**

- Samantha Sirianni,

Cumming School of Medicine, University of Calgary, Calgary T2N4N1, Alberta, Canada

Email: smsirian@ucalgary.ca

-Gregor Wolbring

Department of Community Health Sciences, Cumming School of Medicine, Stream of Community Rehabilitation and Disability Studies Cumming School of Medicine, TRW building 3D31 University of Calgary, 3330 Hospital Drive NW, Calgary, Alberta, Canada (Correspondence) Email: gwolbrin@ucalgary.ca

### Abstract

Occupational therapy and occupational science are two fields that are impacted by innovations and are seen as innovative. Ethical reasoning is seen as essential for guiding innovative processes such as the development of new scientific and technological products. At the same time it is reported that ethicists "lack the appropriate intellectual tools for promoting deep moral change in our society" and that members of the public such as parents of children with disabilities do not necessarily use ethical theories and ethical reasoning to highlight their problems. The purpose of this study was to investigate how the fields of occupational therapy and occupational science engage with ethics within their innovation-covering academic literature and whether occupational therapy and occupational science were mentioned in academic journals that contained words starting with "ethic" in the title. We found little conceptual engagement with ethics principles and no employment of ethical theories in the academic literature covered. We also found little engagement with occupational therapy or occupational science in academic journals that contained words starting with "ethic" in the title. Our findings are another example of the limited use of the term ethics and limited uptake of ethical reasoning using ethical theories giving further weight to the concerns Sherwin voiced.

**Key words:** ethics, ethical theories, ethical reasoning, innovation, science, technology, occupational therapy, occupational science;

### 1. Introduction

Occupational therapy and occupational science focus on improving the health and well-being of people by enabling people to participate in the activities of everyday life [4]. Occupational therapists are responsible to remain current with new developments in the profession and to maintain excellence in their practice [5]. Occupational therapy and occupational science as fields and occupational therapists are continuously impacted by scientific, technological and innovation (STI) developments[6]. Ethical theories and ethical reasoning are employed with local and global scopes when one discusses for example the governance of scientific, technological and innovation (STI) developments [2,7-25].

Ethics is about what one ought to do. However, as Sherwin stated, "we [ethicists] lack the appropriate intellectual tools for promoting deep moral change in our society" ([1] quoted in[2]). Furthermore one study revealed that members of the public such as parents of children with disabilities do not use ethical theories and ethical reasoning to highlight their problems [3]. Our study investigated how the fields of occupational therapy and occupational science engage with ethics within their academic literature covering innovation and whether occupational therapy and occupational science were mentioned in academic journals containing words starting with "ethic" in the title.

### 1.1. Occupational Therapy and Occupational Science

According to the World Federation of Occupational Therapy, "Occupational therapy is the art and science of enabling engagement in everyday living, through occupation; of enabling people to perform the occupations that foster health and well-being; and of enabling a just and inclusive society so that all people may participate to their potential in the daily occupations of life" [4].

Occupational therapists work with people and communities "to enhance their ability to engage in the occupations they want to, need to, or are expected to do, or by modifying the occupation or the environment to better support their

occupational engagement" [26]. In recent years occupational therapy added concepts such as occupational justice [27-29], ecological sustainability of occupations [30], occupational satisfaction [31,32], occupational enablement [33] and other areas [34] to its focus. According to Yerxa, one of the founders of the field occupational science in the 1990's, occupational science is an emerging basic science which supports the practice of occupational therapy [35]. Occupational science is seen to assist in developing the understanding of the occupational nature of humans [36,37] as a method of achieving social justice and social reform [38] and it engages with many occupational concepts (Table 3 in [39]).

### 1.2. Occupational Therapy, Occupational Science and Innovation

The fields of occupational therapy and occupational science both have narratives around innovation. For example, innovation is listed as one value of the Canadian Association of Occupational Therapists [40]. The Canadian Association of Occupational Therapists has an award for innovative practice which is given for "exceptional leadership and innovation in the application of evidence-based principles of occupational therapy to clinical practice" which includes "client service, consumer development, policy community advocacy, development, education and/or fieldwork" [41]. On the webpage of the Canadian Association of Occupational Therapists it is stated that the "nominees shall have had a positive impact on clients, the community and/or the advancement of occupational therapy clinical practice" [41]. Occupational scientists are seen to "study ways of measuring participation, develop new innovative methods of intervention to help individuals engage in activities, and examine the impact of participation on an individual's health and well-being" [42].

### 1.3. Code of Ethics and Occupational Therapy Organizations

Codes of ethics are documents that are developed to give guidance to organizations and groups working under them. The *Canadian Framework for Ethical Occupational Therapy Practice* addresses the ethics principles of autonomy, beneficence, nonmaleficence, and justice [43]. Ethics is used as an umbrella term, combining elements of identity and knowledge, as an everyday way of behaving and what each person values and considers important [43]. The framework primarily discusses the professional ethical conducts that are important for occupational therapists to follow in a way that is

"technically proficient and honors the stories and lived experience of both the therapist and the client" [43].

Occupational therapists are furthermore expected to be courageous, competent, mindful, respectful, sensitive, and reflective when they are working with clients, as occupational therapists are accountable to those they serve and to society [43]. According to the World Federation of Occupational Therapy Code of Ethics, occupational therapists must maintain many personal attributes such as integrity, reliability, open mindedness, and lovalty [44] . Occupational therapists must respect their clients and their unique situation as well as not discriminate against their clients and keep the client information confidential [44]. Occupational therapists must be able to collaborate with other occupational therapists as well as other professions [44]. A combination of knowledge, skills and evidence must be acquired by the occupational therapist to help their clients in the best way as well as to improve their professional field [44]. It also states that the occupational therapy field has to be promoted to the public, other professional organizations and government bodies in an ethical way [44].

#### 1.4 Ethics and Innovation

There are many discourses around innovation and ethics for example medical technology [45], inclusive innovation [46], critical social innovation [47], tripartite innovation for global health [48], sticky ethics and corporate responsibility [49], ethical considerations in the innovation business [50], the politics of blood ethics [51], the ethics of clinical innovation in psychopharmacology [52], legal ethics and technological innovation [53], ethical technology management and innovation [54], and the ethics of innovation [55]. 93% of the articles in the Journal of Responsible Innovation mention words starting with ethic [56]. Empirical ethics and responsible innovation are linked [57] and ethics education is seen as useful for responsible innovation [58].

Given that ethical reasoning is seen as essential for guiding scientific, technological and innovation developments, given Sherwin's concern that ethicists "lack the appropriate intellectual tools for promoting deep moral change in our society" ([1] quoted in[2]) and that members of the public such as parents of children with disabilities do not per se use ethical theories and ethical reasoning to highlight their problems [3] and given that occupational therapy and occupational science see innovation as important for their respective fields, the purpose of this study was to investigated how the fields of occupational therapy and occupational

science engage with ethics within their innovation covering academic literature and whether occupational therapy and occupational science were mentioned in academic journals that contained words starting with "ethic" in the title.

### 2. Data Source and Sampling

We employed three approaches accessing three types of sources to generate descriptive quantitative and qualitative data answering the questions the study posed.

Approach 1: We accessed five occupational therapy journals of different backgrounds (American Journal of Occupational Therapy, British Journal of Occupational Therapy, Canadian Journal of Occupational Therapy, Scandinavian Journal of Occupational Therapy, and Hong-Kong Journal of Occupational Therapy) and the Journal of Occupational Science.

We searched the website search engines of the five occupational therapy journals and the occupational science journal for the term "innovation" in the abstracts of articles on May 5, 2015. We identified n=121 articles from the American Journal of Occupational Therapy, n=129 articles from the British Journal of Occupational Therapy, n=142 from the Canadian Journal of *Occupational Therapy,* n=19 from the *Scandinavian* Journal of Occupational Therapy and n=6 articles from the Hong-Kong Journal of Occupational Therapy and n=41 articles from the Journal of **Occupational** Science. The articles downloaded as PDF and uploaded into Atlas-Ti. 7, a qualitative analysis software, for descriptive quantitative and qualitative content analysis.

**Approach 2:** We accessed three academic databases (EBSCO All - an umbrella database that consists of over 70 other databases including Medline; Scopus and Web of Science) that contain journals that cover a wide range of topics. These databases include many journals that have occupational therapy in the title of the journal such as: British journal of occupational therapy; American iournal of occupational therapy: Australian occupational therapy journal; Physical occupational therapy in pediatrics; Occupational therapy in health care; Physical & occupational therapy in geriatrics; Canadian journal occupational therapy; Scandinavian journal of occupational therapy; Occupational therapy in mental health; Indian journal of physiotherapy & occupational therapy; Occupational international; Indian journal of occupational therapy; Mental health occupational therapy; Occupational therapy journal of research; South

African journal of occupational therapy; New Zealand journal of occupational therapy; Journal of occupational therapy, schools & early intervention; Hong Kong journal of occupational therapy; Irish journal of occupational therapy and Physiotherapy & occupational therapy journal.

We searched (May 19, 2015) the three academic databases for the terms "occupational therapy" and "innovation" in the abstract (EBSCO ALL), abstract, title, keyword (Scopus), Web of Science (topic: meaning Title, Abstract, Author Keyword and Keywords Plus®) limiting the searches to articles, editorial material, review and proceeding papers (Web of Science); review, article, conference paper, editorial (Scopus) and scholarly peer reviewed journals (EBSCO ALL). Of the positive hits n=108 were duplicates from the search conducted in Approach 1 and discarded. The n=71 new articles found were downloaded as PDF uploaded into Atlas-Ti a qualitative analysis for software descriptive quantitative qualitative content analysis.

**Approach 3:** We searched for the presence of the terms "occupational science" and "occupational therapy" in the abstract of articles from journals with words starting with "ethic" in the title of the journal that are listed in *EBSCO All* and *Scopus* (March 3, 2016). We did not use *Web of Science* as it does not generate a hit count for all publications with words starting with "ethic" in the journal title.

### 3. Data Analysis

To obtain descriptive **quantitative data** we employed three approaches.

**Approach 1:** We searched all the downloaded articles obtained as described under section 2.1. Approaches 1 and 2 for terms and phrase containing words starting with "ethic" and using the advanced search feature of the software Adobe Acrobat X Pro to record the numbers of how often a given term or phrase linked to ethics was present in a given article and in how many articles (Table 1).

**Approach 2:** We searched all the downloaded articles obtained as described under section approach 1 and 2 for containing words starting with "ethic", the following n=14 ethics terms: "value". "philosoph\*", "justice". "moral\*", "autonomy", "bioethics", "dignity", "care ethics", "virtue ethics", "feminist ethics", "human ethics", "public health ethics", "beneficence", "maleficence" and n=19 ethical theories: "Kant", "Socialist", "Egalitarian", "Moral Relativism", "Individual Relativism", "Cultural Relativism", "Psychological Hedonism", "Psychological Altruism", "Female Care Ethics", "Virtue Based Theories", "Samuel Pufendorf", "Rights Theory", "WD Ross", "Consequentialism", "Deontology", "Utilitarianism", "Preference Utilitarianism", "Libertarian" and "Feminist Approach". The 34 terms were taken from Beauchamp and Childress' 1979 paper "Principle of Biomedical Ethics" [59] as well as encyclopedia or web sources [60-63].

We used again the advanced search feature of the software Adobe Acrobat X Pro to record the numbers of how often a given term or phrase linked to ethics was present in a given article and in how many articles (Table 2). We also used the advanced search feature of the software Adobe Acrobat X Pro to record how often a term linked to ethics was present in an article within 20 words from a word starting with "inno" (Table 2).

**Approach 3:** We recorded how often the terms "occupational science" and "occupational therapy" were present in the abstract of articles from journals with a word that starts with "ethic" in the title of the journal that are listed in *EBSCO All* and *Scopus* (March 3, 2016) (section 3.1.3.).

The descriptive quantitative data generated by the three approaches was generated by both authors and no discrepancy was evident in counts obtained by the two authors.

To obtain **qualitative data** the downloaded articles were auto-coded for words starting with "inno" which generated n=1075 hits and for words starting with "ethic" which generated n=1442 hits. A co-occurrence code was then generated that indicated the co-occurrence of the two words within 20 words (n=21 quotes). A thematic analysis was performed on the co-occurrence (n=21 quotes) and the n=1442 ethics-related quotes. Both researchers performed the analysis and results were compared between the researchers. No dispute occurred partly due to the few articles that linked content to ethics and related terms.

#### 4. Limitations

Only documents that were in English were considered. We did not cover all the occupational therapy journals in existence and all academic databases that might have articles that cover occupational therapy and occupational science. As such our conclusions are linked to the sources covered and cannot be generalized.

### 5. Results

In a first step we generated descriptive quantitative data on which phrases were linked to words starting with "ethic" (Table 1), which of the n=34 ethics terms mentioned in the section 2.1 were present in the sources covered (Table 2) and how

Table 1. The hit count and the article count for each ethics discourse term, ordered by "Number of Articles in OT Journals" (Second column)

Phrase linked to words starting with ethic	OT Journals Hit Counts	OT Journals Number of Articles (n=417)	OS Journal Hit Counts	OS Journal Number of Articles (n=41)	Database Journal Hit Counts (excluding OT journals already covered)	Database Journal Number of Articles (n=71) (excluding OT journals already covered)
Ethic*	1442	160	56	16	45	23
Ethics approval	530	70	1	1	6	6
Research ethics	212	53	2	2	1	1
Ethics committee	225	46	0	0	4	3
Code of ethics	98	32	0	0	3	2
Ethical consideration	34	18	0	0	1	1
Ethics board	16	15	3	3	0	0
Ethically	25	13	3	2	1	1
Ethical dilemma	14	12	0	0	0	0
Work ethic	11	8	13	2	0	0
Ethical implications	13	8	0	0	0	0
Ethics review	11	7	0	0	1	1
Ethical principles	8	7	0	0	0	0
Ethical obligation	7	7	0	0	0	0
Ethical guideline	8	7	0	0	0	0
Ethics permission	6	6	0	0	0	0
Ethical concern	5	5	0	0	0	0
Ethical decisions	6	5	0	0	0	0
Ethical reasoning	9	4	0	0	0	0
Professional ethics	3	3	0	0	0	0
Ethical standard	5	3	1	1	1	1
Ethical practitioner	2	2	0	0	0	0
Ethical conduct	2	2	0	0	0	0
Ethical question	1	1	0	0	0	0
Ethical belief	1	1	0	0	0	0
Ethical use	1	1	0	0	0	0
Ethical constraints	0	0	1	1	0	0
Protestant Ethics	0	0	2	2	0	0
Interactive ethics	0	0	3	1	0	0
African Ethics	0	0	3	1	0	0

often occupational therapy and occupational science show up in ethics journals.

**Quantitative Data:** Table 1 shows how the term ethics was used in the n=417 occupational therapy and n=41 OS articles. Words and phrases containing words starting with "ethic" were mentioned n=1442 in n=160 occupational therapy articles and n=56 in n=16 OS articles. "Ethical approval" had the highest counts with n=530 in n=70 occupational therapy articles.

Table 2 shows with the hit count and the article count for each of the n=34 ethics discourse terms. It demonstrated that many ethical theories were not employed in the literature investigated, and also that key bioethics principles such as beneficence and maleficence were not employed.

**Mentioning of Occupational Therapy and Occupational Science in Ethics Journals:** Of the 45,588 articles found in the databases that have words starting with "ethic" in the title of journals, n=5 articles mentioned occupational therapy in the

abstract. Not one article mentioned occupational science in the abstract.

**Qualitative Analysis:** Most of the quotations generated for the articles uploaded into Atlas Ti7 contained content that did not engage in a meaningful or conceptual way if at all with the n=34 ethics-related terms in question. As such we only recap here our findings for the quotes generated with words and phrases containing words starting with "ethic". First, we will discuss the ones not linked to innovation within a 20-word distance, and then we will discuss the quotations that co-occurred with "inno\*".

**Ethic\*** and Occupational Therapy: Although n=1442 quotations were generated for words starting with ethic most of the quotations reflect a bureaucratic use of words containing ethic, such as ethics approval or using a term without giving content. Only seven articles were found to have some content.

Table 2. The hit count and the article count for each of the n=34 ethics discourse terms

Term	OT journals Hit Counts	OT journals Number of Articles (n=417)	Number of hits/ articles with terms in proximity (20 words) of term innovation in the database OT articles	OS Hit Counts	OS journal Number of Articles (n=41)	Number of hits/article with terms in proximity (20 words) of term innovation in the OS journal	Database Hit Counts (n=71)	Database OT Number of Articles (n=71)	Number of hits/article with terms in proximity (20 words) of term innovation in the database OT articles
				cs Concep				•	ı
ethic*	1442	160	21/8	56	16	0	45	23	0
Value	1978	269	78/21	254	33	5/2 none linking value with innovation	495	61	0
Philoso*	721	146	2/1	105	22	2/1 (not linking philoso to innovation	236	35	0
Harm	216	92	0	40	15	0	110	29	0
Autonomy	185	76	13/6	8	4	0	26	11	1
Justice	177	58	2/1	64	14	0	74	18	0
moral*	151	61	4/2	35	17	0	67	22	0
Dignity	49	22	0	4	3	0	4	4	0
Beneficence	0	0	0	0	0	0	0	0	0
Maleficence	0	0	0	0	0	0	0	0	0
care ethics	2	2	0	0	0	0	0	0	0
virtue ethics	0	0	0	0	0	0	0	0	0
feminist ethics	0	0	0	0	0	0	0	0	0
public health ethics	0	0	0	0	0	0	0	0	0
bioethics	21	3	0	0	0	0	0	0	0
			Ethic	al Theorie	es				
Egalitarian	7	6	0	3	2	0	0	0	0
Socialist	0	0	0	0	0	0	4	3	0
Hedonism	1	1	0	0	0	0	0	0	0
Libertarian	1	1	0	0	0	0	0	0	0
Feminist Approach	1	1	0	0	0	0	0	0	0
Moral Relativism	0	0	0	0	0	0	0	0	0
Individual Relativism	0	0	0	0	0	0	0	0	0
Cultural Relativism	1	1	0	1	1	0	4	4	0
Psychological Hedonism	0	0	0	0	0	0	0	0	0
Psychological Altruism	0	0	0	0	0	0	0	0	0
Female Care Based Ethics	0	0	0	0	0	0	0	0	0
Virtue Theory	0	0	0	0	0	0	0	0	0
Samuel Pufendorf	0	0	0	0	0	0	0	0	0
Rights Theory	0	0	0	0	0	0	0	0	0
WD Ross	0	0	0	0	0	0	0	0	0
Consequentialism	0	0	0	0	0	0	0	0	0
Deontology	0	0	0	0	0	0	0	0	0
Utilitarianism	0	0	0	0	0	0	0	0	0
Preference Utilitarianism	0	0	0	0	0	0	0	0	0

Abernethy, in her 2010 article *The assessment* and treatment of sensory defensiveness in adult mental health: a literature review, stated that none of the articles in her literature review covered ethical implications [64]. Two articles engaged with the phrase "ethical reasoning". One linked issues of sustainability with occupational therapy philosophy and discusses how employing a sustainability lens with professional reasoning can help practitioners integrate sustainability into their practice [65]. The authors stated: "In addition to addressing issues related to individual client care in our day-to-day practice, occupational therapy practitioners should also consider ethical dimensions of the issues by utilizing the sustainability lens discussed in this paper. This lens encourages practitioners to focus on consequences of our actions and consider our duties, responsibilities, and the morally correct action to be taken, which is an extension of ethical reasoning" [65].

Wendy Wood's article covered the process of curriculum redesign of an occupational therapy Master's degree in which Wood engages with the term "ethical reasoning". Wood states "Ethical reasoning is defined in the curriculum as processes of enacting the highest standards of ethical conduct and of generating solutions to problems on the basis of a systematic study of morality. The article examined current threats to the field "in light of past compromises that weakened occupational therapy's sociopolitical position and diminished its power to meet the occupational needs of people and society" [66].

Taff et al assessed "how contemporary challenges and a need for ethical identity require a philosophical shift"[67] and their article has a section called "Occupational Rights and Human Dignity: Defining Ethics and Accountability" [67]. The phrase "ethical considerations" was mentioned in n=25 articles. However, the phrase was mostly linked to ethics approval. Again, Taff et al provide some content: "There is some debate in recent years about the core values as well as the ethical considerations in the definition and practice of occupational therapy" [67]. Ethical dilemmas were brought to light in one paper where they are "related to an inability to offer new technology to all clients due to funding short falls" [68] whereby the lack of access was seen as being able to be addressed and resolved through public opinion and client experience [68].

Vincent reported on a survey saying that people say ethics is important [69]. However, it was not explained what is meant with ethics. Although the term "ethical implication" was mentioned in n=8 articles in only one case was it not linked to

ethics approval. Castro et al. stated "As culture is difficult to define, and has political and ethical implications, an investigation into its usage is warranted" [70] and flagged the possibility that "a lack of critical insight into professional knowledge increases the risk that occupational therapy will remain satisfied with the current understanding of culture, based on the dominant knowledge. The discipline could fail to address the political, ethical, and theoretical issues required to reach the targeted diversity in its practice" [70].

Taff et. al in their article The Accountability-Well-Being-Ethics framework: A new philosophical foundation for occupational therapy, engage with Rortyian thoughts and they have "particular relevance in occupational therapy, where the focus on possibilities and local meanings resonates heavily with people's lived experience. His contextualism differs from most philosophical perspectives because it is not concerned with great truths. Instead, it is a "lowercase" philosophy that ponders the joys, dilemmas, and improvement of daily life. The discoveries of science are crucial to support the continued growth of professional knowledge. No less important, though, is the philosophical view of the person as an active agent in achieving a good life, and it is equally critical that this facet of occupational therapy be sustained to facilitate both local and global influence. The person-centred philosophy must be nourished, and it is here where Rorty plays a key role. Rorty brings philosophy out of the realm of scientists and academics and presents it as a tool for solving problems and achieving equity in everyday experience. This "lower-case" philosophy requires collaboration, promotes capabilities, and is available to everyone. As such, it is a valuable ally to occupational therapy as the profession seeks ways to address the new challenges of changing health care policies, globalization, and sociopolitical and climate-driven determinants of health. The Rortyian concepts of hope, solidarity. contingency provide new and needed concepts which occupational performance, participation, and well-being can be addressed as we move through the 21st century" [67].

**Ethic\* and Occupational Science:** Words starting with ethic were mentioned in n=16 articles n=56 times with n=6 articles having some content. One article stated that occupational science needs to engage with ethical considerations in order for it to be a socially responsible [71].

According to Rudman, it is important to consider "how occupational science is ethically, morally and politically responsible for the knowledge it generates" which "challenges

occupational scientists to redefine the boundaries between 'professional' (sometimes framed as applied) and 'scientific' (sometimes framed as basic) knowledge and practices" [72] and the "broader dialogue addressing the types of knowledge production falling within the domain and practices of occupational science is essential to optimize relevance and ethical and social responsibility" [72]. Willis link Protestant ethics to social history of deadlines [73].

Halahan states "competence can be regarded as a process\*not merely as an outcome\*and used to enrich practices by opening the arena of human action to its ethical, or value-laden, nature. Participants in occupation become agents of safe, effective, lifegiving, meaningful pursuits, not mere technicians of action, because competence consists as much in people's ability to articulate why they act the way they do as it does in their capacity to act in the first place" [74]. In an article by Elelwani Ramugondo, an ethics idea governing human engagement called Ubuntu, an interactive ethics also called African ethics, is discussed as it is more of a community based ethics rather than just concerning the individual [75]. In this article the Ubuntu "raises consciousness around responsibility of both individuals and communities to allow meaningful existence for all" [75]. This form of ethics governing is concerned with how each individual impacts other individuals [75].

Dickie et al make a case for "Transactional occupational science based on Dewey and his allies" which they assert is "a solid foundation on which to place the concept of occupation" as it "provides a philosophical basis for the importance of occupation in everyday life and because it "enables occupation to be directly related to a wider range of experience and inquiry, from ethics to cultural analysis to political issues such as occupational justice" [76].

**Ethic\* and Innov\*:** N=21 quotations in n=8 occupational therapy articles were generated for the presence of "inno\*" and "ethic\*" within 20 words. All but two articles used the term "ethics approval" and did not use ethics in relation to innovation. No article was obtained for "inno\*" and "ethic\*" within 20 words distance in the occupational science articles.

As to the two occupational therapy articles mentioning "ethic\*" and "inno\*" within 20 words distance; Hoffmann in a 1979 article *Continuing Education: An Answer to Professional Obsolescence* recognized "that new innovations have also fostered a host of problems" [77], stating further that "Organ transplants, for example, have opened a Pandora's Box in terms of ethical questions. The

debate of prolonging life by mechanical means when there is virtually no hope for recovery, has fostered a major debate of the right to die issue. A good example of this situation is the Karen Quinlan case in New Jersey. Another example is biological research on recombinant DNA. It is now possible for scientists to combine genetic material from different molecules and generate biological matter in the laboratory that are not found in nature. Another example is the recent debate concerning test tube fertilization" [77]. However, Hoffman does not explicitly state what the ethical issues are and he does not employ ethical reasoning to discuss some of the specific innovations highlighted.

Anita Atwal's paper stated that "The challenge for action researchers is to act ethically. When instigating change in the health service, investigators must let professionals drive change innovations even though the investigator may find himself or herself challenging assumptions. Action researchers have to ensure that the quality, value and honesty of their inquiries are not jeopardised by unrecognised bias and influence" [78].

#### 6. Discussion

Based on the articles investigated, our findings suggest that the occupational science occupational therapy academic literature around innovation did not engage with ethics in a substantial matter such as employing ethical theories or ethics principles. Further, we found little engagement with occupational therapy and no engagement with occupational science in ethics journals searched. We posit that this is problematic given that occupational therapy and occupational science is seen to be in constant need to innovate [40-42] and given that science and technology products are an area of interest to occupational therapy and occupational science [79-86], products that constantly are influenced by advancements in science and technology. Furthermore, advances in science and technology are seen as innovative and they influence innovation discourses including social innovation. As Jarvis states: "As stated in our Code of Ethics, it is our obligation to keep up to date with changes in our field" [87]. This quote is trying to show the connection that ethics has with innovation in the occupational therapy field [87].

It is also a problem from the perspective of the ethics field. Ethicists want to influence social and political change; but some see problems with doing so. Sherwin recently stated: "We lack the appropriate intellectual tools for promoting deep moral change in our society. To find ways of addressing these difficult questions, we need to learn about the levers of social and political change.

We probably need also to develop skills in communicating effectively with the public and to engage in some version of political lobbying. In other words, we must develop new types of understanding and new ways of practice" ([1] quoted in[2]). Our findings provide evidence for the problem Sherwin outlines. Ethical theories, one of the main tools used in academic ethics discourses to justify certain reasoning and conclusions are not taken up by the occupational therapy and occupational science academic literature. Given our findings, it is reasonable to assume that occupational therapists do not employ ethical theories in their reasoning.

Sherwin asks for the re-orientation of theoretic tools used in bioethics to guide the field in a new direction [1]. She asks for adopting an ethics of responsibility; exploration of the responsibilities of various kinds of actors and relationships among them and the expansion of the types of participants engaged in bioethics ([1] quoted in [2]). We posit that occupational therapy and occupational science based on their focus on occupation deal with many issues that raise 'ethical issues'. As such we posit that the active and knowledgeable involvement of occupational therapy scholars, students, practitioners and occupational science scholars and students is fitting Sherwin's demand. This inclusion however demands that occupational therapy practitioners scholars, students and occupational science scholars and students employ ethical theories and ethical reasoning beyond what we found which we posit means that a curriculum change is needed that trains occupational therapy and occupational science students how to use ethical theories and ethical reasoning. Indeed given emerging science, technology innovation development such as using robots for employment [88] it seems fruitful to develop a community of practice around an "ethics of occupation" a phrase which so far only has 41 hits in Google scholar whereby the focus is not on jobs and being busy but occupation of ones space by

To develop an ethics of occupation as in job, work, and being busy fits with the goal of occupational therapy and occupational science. It also is an pressing issue, given anticipated trends in robotics [88], 3D printing [89-91] and molecular manufacturing (Star Trek food replicator) a process where a machine builds up products atom by atom [92] and areas such as the body enhancements of humans which will impact ability expectations of humans linked to occupation and with that the education of humans [93].

#### 7. Conclusion

Ethics is discussed in relation to innovation for some time. Innovation plays an important role in occupational therapy and innovation science. However, the occupational therapy occupational science literature around innovation did not engage with ethics in a substantial matter such as employing ethical theories, ethics principles and ethical reasoning. More concrete engagement with ethics is needed in occupational science and occupational therapy in order to clarify what is deemed ethical and what ethical issues might arise in terms of innovation in the occupational therapy field.

#### References

- 1. Sherwin, S. Looking backwards, looking forward: Hopesfor bioethic's next twenty five years. *Bioethics* **2011**, *25*, 75-82.
- 2. Wolbring, G. Ethical theories and discourses through an ability expectations and ableism lens: The case of enhancement and global regulation. *Asian Bioethics Review* **2012**, *4*, 293-309.
- 3. Ball, N.; Wolbring, G. Cognitive enhancement: Perceptions among parents of children with disabilities. *Neuroethics* **2014**, *7*, 345-364.
- 4. World Federation of Occupational Therapists.

  Statement on occupational therapy.

  <a href="http://www.wfot.org/Portals/0/PDF/STATEMENT%2">http://www.wfot.org/Portals/0/PDF/STATEMENT%2</a>

  ON%200CCUPATIONAL%20THERAPY%20300811.p
- 5. Canadian Assocation of Occupational Therapists. Professional development.

http://www.caot.ca/default.asp?pageid=14

- 6. Wolbring, G.; Chai, E. Science, technology and innovation governance: An underserved area in occupational therapy and occupational science education, advocacy and research **under review**.
- 7. Buller, P.F.; Kohls, J.J.; Anderson, K.S. The challenge of global ethics. *Journal of Business Ethics* **1991**, *10*, 767-775.
- 8. Gorniak-Kocikowska, K. The computer revolution and the problem of global ethics. *Science and Engineering Ethics* **1996**, *2*, 177-190.
- 9. Twiss, S.B.; Grelle, B. *Explorations in global ethics: Comparative religious ethics and interreligious dialogue.* Westview Press: Boulder, CO, 1998; p 364.
- 10. Plumwood, V. Ecological ethics from rights to recognition: Multipe spheres of justice for human nimal and nature. In *Global ethics and environment*, Low, N., Ed. Routledge: London and New York, 1999; Vol. 12, pp 188-212.
- 11. Langhelle, O. Sustainable development: Exploring the ethics of "our common future". *International Political Science Review / Revue internationale de science politique* **1999**, *20*, 129-149.
- 12. Chiarelli, B. Ethical anthropocentrism: Humanistic ethics and the need for a new global bioethics. *Mankind Quarterly* **2007**, *47*, 105-115.

- 13. ten Have, H.; Ang, T.W. Unesco's global ethics observatory. *Journal of Medical Ethics* **2007**, *33*, 15-16.
- 14. Pogge, T.W.M.; Moellendorf, D.; Horton, K. *Global responsibilities: Global ethics: Seminal essays.* Paragon House: 2008.
- 15. Crocker, D.A. *Ethics of global development: Agency, capability, and deliberative democracy.* Cambridge Universiy Press: Cambridge, UK 2009; p 432.
- Sass, H.M.; Xiaomei, Z. Global bioethics: Eastern or western principles? Asian Bioethics Review 2011, 3, 1-2.
- 17. Ryan, C. The dialogue of global ethics. *Ethics & International Affairs* **2012**, *26*, 43-47.
- 18. Illingworth, P. Ethics and social capital for global well-being. *International Review of Economics* **2012**, *59*, 389-407.
- 19. Özdemir, V.; Joly, Y.; Kirby, E.; Avard, D.; Knoppers, B.M. Chapter 11 beyond elsis: Where to from here? From "regulating" to anticipating and shaping the innovation trajectory in personalized medicine. In *Pharmacogenomics*, Lam, Y.-W.F.; Cavallari, L.H., Eds. Academic Press: San Diego, 2013; pp 405-428.
- 20. Sunderland, M.E.; Taebi, B.; Carson, C.; Katenberg, W. Teaching global perspectives: Engineering ethics across international and academic borders. *Journal of Responsible Innovation* **2014**, *1*, 228-239.
- 21. Various. *Science and technology governance and ethics: A global perspective from europe, india and china*. Springer: New York, NY, 2015.
- 22. Gaskarth, J. *Rising powers, global governance and global ethics*. Routledge: London and New York 2015.
- 23. Stemerding, D.; Rerimassie, V.; van Est, R.; Zhao, Y.; Chaturvedi, S.; Ladikas, M.; Brom, F.W. A comparative framework for studying global ethics in science and technology. In *Science and technology governance and ethics*, Ladikas, M.; Chaturvedi, S.; Zhao, Y.; Stemerding, D., Eds. Springer: New York, Ny, 2015; pp 99-110.
- 24. Fukuda-Parr, S.; McNeill, D. Post 2015: A new era of accountability? *Journal of Global Ethics* **2015**, 1-8.
- 25. UNESCO. Ethics of science and technology. http://en.unesco.org/themes/ethics-science-and-technology
- 26. World Federation of Occupational Therapists. Statement on occupational therapy. <a href="http://www.wfot.org/Portals/0/PDF/STATEMENT%2">http://www.wfot.org/Portals/0/PDF/STATEMENT%2</a> <a href="http://www.wfot.org/Portals/0/PDF/STATEMENT%2">00N%200CCUPATIONAL%20THERAPY%20300811.p</a> <a href="http://df">df</a>
- 27. Townsend, E.; Wilcock, A.A. Occupationaljustice and client-centred practice: A dialogue in progress. *Canadian Journal of Occupational Therapy* **2004**, *71*, 75-87.
- 28. Townsend, E.; Polatajko, H. *Enabling occupation ii: Advancing an occupational therapy vision for health, well-being, & justice through occupation.* 2nd ed.; CAOT Publicationa: Ottawa, ON, 2013.
- 29. Durocher, E.; Rappolt, S.; Gibson, B.E. Occupational justice: Future directions. *Journal of Occupational Science* **2013**, *21*, 431-442.
- 30. Wagman, P. How to contribute occupationally to ecological sustainability: A literature review. *Scandinavian journal of occupational therapy* **2014**, *21*, 161-165.

- 31. Atwal, A.; Owen, S.; Davies, R. Struggling for occupational satisfaction: Older people in care homes. *The British Journal of Occupational Therapy* **2003**, *66*, 118-124.
- 32. VanLeit, B.; Crowe, T.K. Outcomes of an occupational therapy program for mothers of children with disabilities: Impact on satisfaction with time use and occupational performance. *American Journal of Occupational Therapy* **2002**, *56*, 402-410.
- 33. Polatajko, H. The evolution of our occupational perspective: The journey from diversion through therapeutic use to enablement. *Canadian Journal of Occupational Therapy* **2001**, *68*, 203-207.
- 34. Kronenberg, F.; Pollard, N.; Sakellariou, D. *Occupational therapies without borders-volume 2: Towards an ecology of occupation-based practices.* Elsevier Health Sciences: 2011; Vol. 2.
- 35. Yerxa, E.J. An introduction to occupational science, a foundation for occupational therapy in the 21st century. *Occupational Therapy and Healthcare* **1990**, 6, 1-17.
- 36. Wilding, C.; Whiteford, G. From practice to praxis: Reconnecting moral vision with philosophical underpinnings. *The British Journal of Occupational Therapy* **2009**, *72*, 434-441.
- 37. Canadian Society of Occupational Scientists. What is occupational science. https://sites.google.com/site/occupationalsciencecana da//occupational-science/what-is-occupational-science
- 38. Molke, D.K.; Laliberte-Rudman, D.; Polatajko, H.J. The promise of occupational science: A developmental assessment of an emerging academic discipline. *Canadian Journal of Occupational Therapy* **2004**, *71*, 269-280.
- 39. Tsing-Yee (Emily), C.; wolbring, G. The portrayal of occupational therapy and occupational science in canadian newspapers: A content analysis. *Societies* **2016**, *6*, accepted.
- 40. Canadian Association of Occupational Therapists.
  About caot. <a href="http://www.caot.ca/default.asp?pageid=2">http://www.caot.ca/default.asp?pageid=2</a>
- 41. Canadian Association of Occupational Therapists. Award for innovative practice. http://www.caot.ca/default.asp?pageid=1363
- 42. University of British Columbia. What is occupational science & occupational therapy? http://osot.ubc.ca/about/what-is-os-ot/
- 43. Canadian Association of Occupational Therapists. The canadian framework for ethical occupational therapy
  - $\underline{http://www.caot.ca/pdfs/ethicalframeworkjuly2006.p}\\ \underline{df}$
- 44. World Federation of Occupational Therapists. Code of ethics.
- http://www.wfot.org/ResourceCentre/tabid/132/did/34/Default.aspx
- 45. Chojnacki, M.; Wójcik, A. Security and the role of new technologies and innovation in medical ethics. *Organizational Culture and Ethics in Modern Medicine* **2015**, 52.
- 46. Munoz, P.; Kimmitt, J. Re-thinking the ethics of inclusive innovation. **2015**.

- 47. Casado da Rocha, A.; Calzada, I. Demos-ethos: A framework to study the icelandic and basque cases through critical social innovation and applied ethics. *Innovation: The European Journal of Social Science Research* **2015**, *28*, 425-442.
- 48. Dove, E.S.; Barlas, İ.Ö.; Birch, K.; Boehme, C.; Borda-Rodriguez, A.; Byne, W.M.; Chaverneff, F.; Coşkun, Y.; Dahl, M.-L.; Dereli, T. An appeal to the global health community for a tripartite innovation: An "essential diagnostics list," "health in all policies," and "seethrough 21st century science and ethics". *Omics: a journal of integrative biology* **2015**, *19*, 435-442.
- 49. Torres, D.L. Sticky ethics, innovation, and corporate responsibility. *SAM Advanced Management Journal* **2015**, *80*, 12.
- 50. Fassin, Y. Innovation and ethics ethical considerations in the innovation business. In *Business challenging business ethics: New instruments for coping with diversity in international business*, Springer: 2000; pp 193-203.
- 51. Stokes, E. The politics of blood: Ethics, innovation and the regulation of risk. *Medical Law Review* **2015**, *23*, 164-170.
- 52. Ghaemi, S.N.; Goodwin, F.K. The ethics of clinical innovation in psychopharmacology: Challenging traditional bioethics. *Philosophy, Ethics, and Humanities in Medicine* **2007**, *2*, 26.
- 53. Zorza, R. Re-conceptualizing the relationship between legal ethics and technological innovation in legal practice: From threat to opportunity. *Fordham L. Rev.* **1998**, *67*, 2659.
- 54. Norcia, V.d. Ethics, technology development, and innovation. *Business Ethics Quarterly* **1994**, *4*, 235-252.
- 55. Lee, E. The ethics of innovation: P2p software developers and designing substantial noninfringing uses under the sony doctrine. *Journal of Business Ethics* **2005**, *62*, 147-162.
- 56. Holitzki Hannah; Wolbring Gregor. Responsible innovation and ethics: A need for globalization. **under review**.
- 57. Gardner, J.; Williams, C. Responsible research and innovation: A manifesto for empirical ethics? *Clinical Ethics* **2015**, 1477750914567840.
- 58. Spruit, S. Responsible innovation through ethics education: Educating to change research practice. *Journal of Responsible Innovation* **2014**, *1*, 246-247.
- 59. Beauchamp, T.L.; Childress, J.F. *Principles of biomedical ethics*. Oxford University Press: 2001.
- 60 Internet Encyclopedia of Philosophy. Ethics | internet encyclopedia of philosophy.
  - http://www.iep.utm.edu/care-eth/
- 61. Peacock, K. Ethical theories. http://classes.uleth.ca/200303/phil3406b/Ethical\_Theories.html (Aug 2, 2015),
- 62. Scott. Annotated list of ethical theories. http://files.meetup.com/1715539/Annotated%20List%20of%20Ethical%20Theories.pdf and http://www.meetup.com/History-of-Philosophy/messages/boards/thread/24479582
- 63. Cushman, R. Ethics terms and terminology. http://www.lasalle.edu/~price/Hon%20365%20ethics%20terms.htm (Aug 2, 2015),

- 64. Abernethy, H. The assessment and treatment of sensory defensiveness in adult mental health: A literature review. *The British Journal of Occupational Therapy* **2010**, *73*, 210-218.
- 65. Dennis, C.W.; Dorsey, J.A.; Gitlow, L. A call for sustainable practice in occupational therapy un appel à la pratique durable en ergothérapie. *Canadian Journal of Occupational Therapy* **2015**, 0008417414566925.
- 66. Wood, W.; Nielson, C.; Humphry, R.; Coppola, S.; Baranek, G.; Rourk, J. A curricular renaissance: Graduate education centered on occupation. *American Journal of Occupational Therapy* **2000**, *54*, 586-597.
- 67. Taff, S.D.; Bakhshi, P.; Babulal, G.M. The accountability-well-being-ethics framework: A new philosophical foundation for occupational therapy le cadre accountability-well-being-ethics: Un nouveau fondement philosophique pour l'ergothérapie. *Canadian Journal of Occupational Therapy* **2014**, *81*, 320-329.
- 68. Fisher, G.S. The status of occupational therapy education in the 90s'. *Occupational therapy in health care* **2000**, *12*, 1-15.
- 69. Vincent, C. Towards the development of a policy of recycling assistive technology for people living with a disability. *The British Journal of Occupational Therapy* **2000**, *63*, 35-43.
- 70. Castro, D.; Dahlin-Ivanoff, S.; Mårtensson, L. Occupational therapy and culture: A literature review. *Scandinavian journal of occupational therapy* **2014**, *21*, 401-414.
- 71. Gage, M. Re-engineering of health care: Opportunity or threat for occupational therapists? *Canadian Journal of Occupational Therapy* **1995**, *62*, 197-207.
- 72. Rudman, D.L.; Dennhardt, S.; Fok, D.; Huot, S.; Molke, D.; Park, A.; Zur, B. A vision for occupational science: Reflecting on our disciplinary culture. *Journal of Occupational Science* **2008**, *15*, 136-146.
- 73. Willis, E. Deadlines and the purgatorial complex. *Journal of Occupational Science* **2000**, *7*, 128-132.
- 74. Holahan, L.F. Quality-in-doing: Competence and occupation. *Journal of Occupational Science* **2014**, *21*, 473-487.
- 75. Ramugondo, E.L.; Kronenberg, F. Explaining collective occupations from a human relations perspective: Bridging the individual-collective dichotomy. *Journal of Occupational Science* **2013**, *22*, 3-16.
- 76. Dickie, V.; Cutchin, M.P.; Humphry, R. Occupation as transactional experience: A critique of individualism in occupational science. *Journal of Occupational Science* **2006**, *13*, 83-93.
- 77. Hoffman, A.M. Continuing education: An answer to professional obsolescence. *Canadian Journal of Occupational Therapy* **1979**, *46*, 211-213.
- 78. Atwal, A. Getting the evidence into practice: The challenges and successes of action research. *The British Journal of Occupational Therapy* **2002**, *65*, 335-341.
- 79. Angelo, J.; Buning, M.E.; Schmeler, M.; Doster, S. Identifying best practice in the occupational therapy assistive technology evaluation: An analysis of three focus groups. *American Journal of Occupational Therapy* **1997**, *51*, 916-920.

- 80. Kjeken, I. Measurement in occupational therapy. *Scand. J. Occup. Ther.* **2012**, *19*, 466-467.
- 81. Trefler, E. Technology applications in occupational therapy. *The American journal of occupational therapy.:* official publication of the American Occupational Therapy Association **1987**, 41, 697-700.
- 82. Edyburn, D. Rethinking assistive technology. *Special Education Technology Practice* **2004**, *5*, 16-23.
- 83. Nilsson, I.; Townsend, E. Occupational justice—bridging theory and practice. *Scandinavian Journal of Occupational Therapy* **2010**, *17*, 57-63.
- 84. Eek, M.; Wressle, E. Everyday technology and 86-year-old individuals in sweden. *Disability and Rehabilitation: Assistive Technology* **2011**, *6*, 123-129.
- 85. Kottorp, A.; Nygård, L.; Hedman, A.; Öhman, A.; Malinowsky, C.; Rosenberg, L.; Lindqvist, E.; Ryd, C. Access to and use of everyday technology among older people: An occupational justice issue but for whom? *Journal of Occupational Science* **2016**, 1-7.
- 86. Copley, J.; Ziviani, J. Barriers to the use of assistive technology for children with multiple disabilities. *Occup. Ther. Int.* **2004**, *11*, 229-243.
- 87. Jarvis, H. Should continuing education be mandatory? *Canadian Journal of Occupational Therapy* **1989**.
- 88. Wolbring, G. Employment, disabled people and robots: What is the narrative in the academic literature and canadian newspapers? . *Societies* **2016**, *6*, online.
- 89. Kennedy, E.J.; Giampetro-Meyer, A. Gearing up for the next industrial revolution: 3d printing, home-based factories, and modes of social control. *Loy. U. Chi. LJ* **2014**, *46*, 955.
- 90. Kim, H.-C. A study on the socio-economic impact of 3d printing. *Journal of Digital Convergence* **2015**, *13*, 23-31.
- 91. Spaeth, S.; Hausberg, P. Can open source hardware disrupt manufacturing industries? The role of platforms and trust in the rise of 3d printing. In *The decentralized and networked future of value creation*, Springer: 2016; pp 59-73.
- 92. Wolbring, G. Lego atoms and base pairs. In *Imagining science*, Caulfield, T.; Caulfield, S., Eds. University of Alberat Press: Edmonton, Alberta, Canada, 2008.
- 93. Wolbring, G.; Yumakulov, S. Education through an ability studies lens. *Zeitschrift für Inklusion* **2015**, *10*, no page number.

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### On Being the Hippocratic Doctor: Views of House officers in a Nigerian Teaching Hospital

- Onochie Okoye

Department of Ophthalmology, College of Medicine, University of Nigeria, PMB 01129, Enugu, Nigeria Email: onochie.okoye@unn.edu.ng

- Ferdinand Maduka-Okafor

Department of ophthalmology, College of Medicine, University of Nigeria

- Anthonia Udeaja

Department of ophthalmology, Anambra State University Teaching Hospital, Awka, AnambraState, Nigeria

- Abali I Chuku

Federal Medical Center, Umuahia, Nigeria

### **Abstract**

Medical students in many countries take a medical oath on graduation from medical school. Given that there is little or no formal medical ethics education in many Nigerian medical schools, the current relevance of swearing to these medical oaths is being questioned. This study determined mainly the views of pre-registration house officers (PRHOs) on the relevance of the Hippocratic-based medical oaths and some selected issues related to ideals espoused therein. Using administered questionnaires, a cross-sectional survey of PRHOs was conducted in 2013 as a preorientation workshop activity in Respondents were simply required to indicate if they agreed/disagreed with 29 perception statements related to the medical oaths and their ideals. Simple descriptive analysis was done using the Statistical Package for Social Sciences version 19. The sample included 63 males and 41 females. who had all sworn to the Physician's Oath at their 9 respective medical schools. Though only two respondents (1.9%) were confident about reciting the Physician's oath/any medical oath from memory or recalling all the specific details contained in it, the majority of them agreed with all the traditional ideals espoused in the Hippocraticbased oaths, including the prohibitions on abortion, euthanasia/physician-assisted suicide and sexual misconduct. Contemporary issues like doctors' strike actions, job security/self-preservation issues and demand for payment of hospital fees before service were shown to be contentious issues for which there was no explicit guidance from the medical oaths. For these oaths to gain greater relevance and priority among these doctors, they should be recited within the context of a reformed undergraduate medical educational system with an integrated medical ethics curriculum and a functional health care system that is responsive and sensitive to societal needs and changes.

#### 1. Introduction

Although oath taking is common in many societies, its importance and impact varies among the major professions, with the taking of the Hippocratic oath being widely invoked in the popular medical culture as being contributory to conveying a direction to medical practice and the medical profession [1]. Most medical graduates will take a medical oath to inspire them to take their proper place in the comradeship of physicians and remind them of their obligations to their patients, society and their profession [2]. The recitation of such an oath is a laudable tradition that provides a link to the history of medicine, affirms the solemnity of a medical career, and acknowledges the public's trust in doctors[3].

Included in the classical Hippocratic Oath are content domains espousing loyalty to colleagues, and teachers, protecting patient profession confidentiality, avoiding sexual misconduct, nonexploitation of patients, prohibition of abortion, prohibition of physician assisted suicide or euthanasia, putting the patient's welfare first, acting with beneficence or non-maleficence, professional integrity, acknowledgement of limits of competence and willingness to refer to specialized colleagues, furthering a just society, respecting the law and/or laws of humanity, avoiding bias or prejudice, and commitment to peace[4]. With growing attention and interest in medical oaths, the medical profession has witnessed the creation and use of both Hippocratic and non-Hippocratic based oaths, with some of the latter often times being authored by medical students and/or clinical faculty and projecting some of the ideals in the original Hippocratic oath [4]. One such variant, generally considered as the modern version of the Hippocratic oath and widely used, is the World Medical Association (WMA) Declaration of Geneva's Physicians Oath [5]. Embodied in this declaration are the guidelines for behavioral interaction between practitioners and their patients, practitioners and their teachers, practitioners and their colleagues, as well as practitioners and humanity/society as represented by law and the government.

In Nigeria, all fresh medical graduates on formal induction into the medical profession are required to publicly declare their readiness to obey the professional rules and regulations (Code of Medical Ethics in Nigeria) of the Medical and Dental

Council Of Nigeria (MDCN-the regulatory body for medical and dental practice) and all other laws for the control of the medical profession, as well as subscribe to the Physicians' Oath [6], these being the core of medical ethics and professionalism in the country. All the newly inducted doctors are consequently given personal copies of the Code of Medical Ethics booklet together with their professional temporary registration licenses but it is doubtful if this actually generates a commensurate level of interest in medical ethics.

Incidentally, there is no documented formal undergraduate medical ethics and professionalism education program that is actively implemented in most Nigerian medical schools. Undergraduate medical education remains largely focused on traditional clinical and basic medical science components, leaving students to develop moral attitudes passively through observation and intuition [7], a situation worthy of note given that paternalism is still very much alive and well in many of the routine doctor-patient interactions in the Nigerian society. Even when ethics instructions had been given, anecdotal evidence points to these being very inconsistent and the specific teaching on these medical oaths being highly variable.

Against this backdrop, the current relevance of swearing to these medical oaths is being questioned, particularly when these young doctors are compelled into participating in these oath taking ceremonies. There is paucity of evidence in our settings on how much of these declarations are retained, recalled and applied by these young doctors in the course of their duties. As a preliminary step to developing a curriculum for undergraduate medical ethics in Nigeria, our study determined the views of pre-registration house officers (PRHOs) on the relevance of the medical oaths and some selected issues explicitly or implicitly related to the ideals espoused in these Hippocratic-based medical oaths.

### 2. Methods

A descriptive cross-sectional survey of preregistration house officers(PRHOs) was conducted in 2013 as a pre-workshop activity for the orientation workshop on the "Doctor-Patient Relationship" organized for the fresh intake of PRHOs for a teaching hospital in Nigeria. Selfadministered 37-item anonymous questionnaires were distributed among all the eligible and willing workshop participants and, the completed ones were consequently retrieved on-the-spot by the research assistants after 30 minutes. **Table 1:** The views of 104 PRHOs on statements

regarding medical oaths

Perception statement	Agree (%)	Disagree (%)	Not sure (%)
Hippocratic oath or the physician's oath are still relevant to modern medicine	75(72.1)	14(13.5)	15(14.4)
The current medical oaths should be revised in the face of emerging & evolving trends in medicine & society	68 (65.4)	21 (20.2)	15 (14.4)
Medical schools should abrogate the medical oaths	17 (16.4)	64 (61.5)	23 (22.1)
Graduating doctors should write their personal oaths	14 (13.5)	79 (75.9)	11 (10.6)
Oath taking ceremonies automatically commit doctors to ethical conduct & practice	52 (50)	41 (39.4)	11 (10.6)
A pan-professional oath for all health workers is desirable, since modern health care is multidisciplinary	68 (65.4)	22 (21.1)	14 (13.5)

Respondents were simply required to indicate if they agreed/disagreed with 29 perception statements related to the relevance of the medical oaths and the ideals espoused in these Hippocraticbased medical oaths (specifically the Physician's declaration and the Hippocratic Oath). The responses to these statements were initially based on a 5 point Likert scale: 1=strongly disagree, 2=disagree, 3=not sure, 4=agree and 5=strongly agree, and subsequently grouped into 3 categories: 1 and 2=disagree, 3=not sure, and 4 & 5=agree. Frequencies, proportions and percentages were generated on these responses, using the Statistical Package for Social Sciences SPSS Version 19. Questionnaires with incomplete entries were excluded from analysis. Approval for the study was obtained from the Health Research Ethics Committee of a university Teaching Hospital in Nigeria.

**Table 2:** The views of 104 Pre-registration house-officers on statements on certain ideals guiding professional practice

Perception statement	Agree (%)	Disagre e (%)	Not sure (%)
A doctor's life should be entirely consecrated to the service of humanity devoid of any other considerations	80 (76.9)	11 (10.6)	13 (12.5)
Medicine must be practiced always with respect, conscience, dignity, integrity & honour	102 (98.1)	Nil	2 (1.9)
Doctors should only undertake interventions within their professional competence	96 (92.3)	6 (5.8)	2 (1.9)
Job security and self- preservation should be of secondary concern to doctors	39 (37.5)	37 (35.6)	28 (26.9)
Doctors should never embark on industrial strike actions	37 (35.6)	31 (29.8)	36 (34.6)
Doctors should always abstain from any mischief or corruption	103 (99)	Nil	1 (1)

#### 3. Results

The sample included 63 males and 41 females, with a response rate of 94.6% (104/110). All the respondents had trained in 9 different medical schools within Nigeria. The mean (SD) age was 26.2 (2.7) years. All the respondents identified Christianity as their religion. All had participated in a mandatory medical oath-taking ceremony, on graduation from their respective medical schools. Though all stated that they were aware of the original Hippocratic Oath and/or the Physician's Oath, only two respondents (1.9%) were confident about reciting the Physician's Oath/any medical oath from memory or recalling all the specific details contained in it. Tables 1 to 4 show the views of the 104 respondents on the 29 perception statements presented in the questionnaire.

**Table 3:** The views of 104 pre-registration houseofficers on statements on ideals related to the doctor-

patient relationship

patient relationship		D.	NT /
Perception statement	Agree (%)	Disa gree	Not sure
	()	(%)	(%)
A doctor must act in the best	95	4	5
interests of the patient always	(91.3)	(3.9)	
1	, ,	, ,	` /
A doctor must act to avoid	93	4	7
causing any form of harm to the	(89.4)	(3.9)	(6.7)
patient always			
A doctor should not use his	87	4	13
medical knowledge to assist in	(83.6)	(3.9)	(12.5)
the termination of a patient's			
life(Euthanasia etc)			
	()		
A doctor should not act to	78 (75)	8	18
terminate a viable pregnancy		(7.7)	(17.3)
A do ator must hold all	07	6	11
A doctor must hold all	87	(5.8)	(10.6)
information about his patients in	(83.6)	(5.8)	(10.6)
confidentiality always, even after death			
death			
A doctor should not insist on	38	30	36
payment before attending to any	(36.5)	(29)	(34.6)
patient	(30.5)	(2))	(3 1.0)
<b>r</b>			
A doctor should not issue a	91 (87)	8	5
certificate of medical fitness	` '	(7.7)	(4.8)
without conducting the necessary			
examinations			
A doctor should not issue a sick	89	6	9(8.6)
leave certificate to any	(86)	(5.8)	
undeserving patient, irrespective			
of the situation			
A de casa also al direct remonanile a	77 (74)	17	10
A doctor should not prescribe	77 (74)	17	
treatment over the telephone or email without first seeing and		(10)	(9.6)
examining the patient			
examining the patient			
A doctor should avoid all	98 (94)	2.	4
intimate relationships with one's	, (, 1)	(1.9)	
patients		(2.7)	(2.7)
F			

### 4. Discussion

With significant shifts in the traditional moral grounds of the society against the background of scientific/technological advances, the medical profession is increasingly being required to face hard choices in patient care and to re-examine its own role in health care and the nature of its values [8]. The medical oaths, be it the modernized Hippocratic oath, Declaration of Geneva, Prayer of Maimonides, oath of Louis Lasagna or other variants [9], are thus being re-appraised afresh for both moral and professional guidance. The main intention of a medical oath seems to be to declare the core values of the medical profession and to strengthen the necessary resolve in doctors to exemplify professional integrity [8]. However, with consideration of increasing religious governmental issues which impinge on professional behavior, concerns over the moral nature of medical education and practice are being brought to prominence by students, practitioners, and faculty. Oaths are deontological in that they bind the oath-taker to certain kinds of duties and obligations, and partaking in such is regarded as a symbolic, integral and shared aspect of professionalization [4]. By providing the oathtaking young doctor with a set of general ethical precepts and prohibitions, he is then expected to apply such to situations arising in daily medical practice and interactions.

**Table 4:** The views of the 104 PRHOs on perception statements regarding relationship with teachers, colleagues & students/trainees.

Perception statement	Agree (%)	Disa gree( %)	Not sure (%)
A doctor should show all his teachers unconditional respect & gratitude, which is their due	91	6	7
	(88)	(5.8)	(6.7)
A doctor should help all his teachers in professional matters, if & when required	89 (85)	4 (3.8)	11 (10. 6)
A doctor should help all his teachers in other matters, if & when required.	72	15	17
	(69)	(14)	(16)
A doctor should relate with all other doctors as family, & not merely as colleagues	77	9	18
	(74)	(8.7)	(17)
A doctor should impart medical knowledge only to those students, trainees & colleagues he considers responsible and serious	19	65	20
	(18)	(63)	(19)
A doctor should impart medical knowledge to any student, trainee or colleague wishing to learn	97 (93)	3 (2.9)	4 (3.8)
A doctor should avoid intimate relationships with one's students or trainees.	91	4	9
	(88)	(3.8)	(8.7)

Oath-taking among professionals ubiquitous practice and even among Africans, the concept is enshrined in the idea that it is usually a ceremony of great solemnity and a public attestation of the veracity and sincerity of the swearer's words and actions. Yet, as the use of the modern medical oaths has burgeoned, their contents have veered away in so many ways from the original oath's basic tenets. Many contemporary oaths seem diluted and the lack of enforceable sanctions for defaulters seemingly render them toothless in their impact. A growing number of practitioners had come to feel that the Hippocratic Oath is inadequate to address the realities of a medical world that has witnessed huge scientific, economic, political and social changes; and that the principles enshrined in the oath do not constitute a shared core of moral values for adherents of other religions, considering its pagan origins. With all these in mind, some doctors see oath-taking as little more than a pro-forma nostalgic ritual with little value beyond that of upholding tradition, being a near-meaningless formality devoid of any influence on how medicine is truly practiced in the real world [10].

Our study demonstrated that all the medical schools attended by the respondents administered the Physician's Oath to their graduates, in line with the requirements of the Medical and Dental Council of Nigeria (MDCN). Though the Physician's Oath is a modernized form of the classical Hippocratic Oath, it differs mainly from the original version in not making reference to God or any deity, sexual misconduct. abortion. euthanasia/physicianassisted suicide and possibility of consequences for failure to live up to the stated ideals. This use of only the Physician's Oath in these oath-taking ceremonies is very much unlike the situation in some other parts of the world, where various forms of oaths were used, with some versions being authored by the students and some schools even offering their students a menu of oaths to pick from for use in graduation ceremonies and other relevant events [4].

Studies have shown that over the last couple of decades the prevalence of oath taking in U.S medical schools had grown remarkably from only 28% in 1928 to involve all allopathic schools and osteopathic schools by 1993 [11], with only 1.6% of 100 allopathic schools using the Declaration of Geneva and 21.3% using a modified Declaration of Geneva in 1993 [4]. On another note, a contemporary medical ritual called the white coat ceremony is now being practiced at more than 100 American medical schools, in which first year medical students publicly vow to abide by the

medical oaths occasionally authored by the students and/or faculty [12].

The degree of importance which these graduating students attach to these medical oaths had also been called to question at various times. In our study, virtually none of the PRHOs was confident about reciting the contents of any medical oath by memory or recalling all the specific details, a situation corroborated in other studies where it was stated that the contents of the medical oath sworn to were often soon forgotten [13,14]. On the contrary, those students who had formally studied the medical oath were shown to have a better recall of its principles [14]. In line with that finding, it was suggested that, at a minimum, the last hours of medical school education be devoted to a formal study of the Hippocratic Oath [14]. Thus, the role of medical oaths in the ethical education of undergraduate medical students will need to be reassessed in our medical schools, if these young doctors are to stop regarding these oath-taking exercises as mere ritualistic recitations. The need for formal instructions is buttressed further by the assertions of majority of our respondents that the medical oaths are still relevant to modern medicine and as such, should not be abrogated.

Further analysis of their views on the medical oaths (Table I) shows a preference for a revision of the medical oath to align with evolving trends in medicine and society, without necessarily expecting graduating doctors to write their personal or preferred oaths. The use of non-standard oaths may make oaths and oath taking more relevant and useful as means of promoting professionalism but it may also lead to fragmentation and confusion about the ethical values of the medical profession, thereby diluting the value of a professionally binding oath.

At our level of National development, offering students a menu of oaths to select from as practiced in the western world may further worsen the situation as mixed messages will be sent out to these students from time to time, erroneously conveying the impression that medical oaths are flexible documents which can be framed in any form to suit the oath-taker [4]. Such a situation may not augur well for the ethical and professional development of these young doctors, given that they had little or no formal medical ethics teaching as undergraduates. With respect to possible revisions required on the currently Physician's oath and the oath-taking ceremony, further qualitative studies are imperative, involving the MDCN, medical educators, policy makers, administrators, medical practitioners, patients as well as the students. The development and use of a more socio-culturally sensitive and relevant oath

may also enhance the importance and relevance of these medical oaths to these graduating doctors.

Also, worthy of note is the view held by the majority of respondents about the desirability of a pan-professional code. If such were to promoted, it could engender a positive degree of moral cohesion between all caring professions, across institutional boundaries. influencing perhaps organization of health care [8]. The hope is that a single oath for all health care professions could heal split loyalties and ameliorate existing moral tensions in health care [8]. However, this may only worthy consideration with the cooperation of all the other stakeholders in the health care sector, and may not be currently feasible in Nigeria considering the prevailing level of inter-professional disharmony in the health sector.

The Hippocratic Oath's timelessness as a touchstone of medical care rests in an emphasis on the values of an "ideal physician" [15], even though one may not know to what extent these values are actually taught in the medical schools. There is no reference in it or other variants to the facts and skills that a doctor must know, only to the behaviors expected in the practice of medicine [15]. Although there is paucity of data on the impact of medical oaths upon oath-takers' behaviors, a study in Israel showed that the medical students doubted the oath's influence [16]. Analysis of the views of the PRHOs on the perception statements (Tables 2 to 4) in our study indicate a reasonable level of agreeability with the ideals espoused in the medical oaths. Though oaths may not compel behavior, they may serve to sensitize the oath-taker to the ethically or professionally appropriate choices inherent in any interaction. There may be a discrepancy between the respondents' standpoints on the perception statements and their actual behavior in their everyday practice. Though the questionnaires were self-administered anonymous, it is still possible that the frequency of agreement with those statements in support of the ideals espoused in these oaths might be overestimated due to social desirability effect.

Given that the Physician's Oath does not make any explicit references to sexual misconduct, abortion and euthanasia unlike the classical Hippocratic Oath, their responses on the related perception statements are apparently indicative of these doctors' belief that their first responsibility is to care for their patients, acting as a fiduciary for the patient and keeping with the traditional Hippocratic moral obligation of providing net medical benefit to the patient without causing harm in any form. In addition, the underlying influences of their Christian and socio-cultural beliefs

regarding the sanctity of life and the fact that abortion and euthanasia are illegal in Nigeria are obviously contributory to the views expressed. Regarding sexual relationships between doctors and patients or between doctors and their students, these issues are still subjects of ethical and legal analysis in many places and their inclusion in the modern medical oaths is still being debated globally [17].

One criticism some people have against many of the medical oaths is their perceived failure to keep up with contemporary issues in society and the medical profession. Legally, however, medical doctors in Nigeria are not held strictly accountable as fiduciaries as they may also have obligations and allegiance to other parties such as the Nigerian Medical Association and the National Association of Resident Doctors. In a society grappling with changes characterized by unionization of the medical profession, institutionalization depersonalization of health care, incessant industrial strike actions and competition within the health sector, advertising/commercialization of practice, and specialization in medicine, it is becoming more imperative that graduating doctors be provided with the requisite knowledge and skills for navigating through this emerging and evolving landscape of ethical and professional challenges.

The pattern of responses (evenly distributed across the three categories of responses) observed in relation to 3 perception statements on doctors' involvement in strike actions, job security/self-preservation issues (Table 2) and demand for payment of hospital fees before service(Table 3) shows a gap in knowledge and some level of conflict among the significant proportions of the study sample with respect to identifying the expected behavior in those circumstances as prescribed by the tenets of the medical oaths or the code of medical ethics, given that these oaths do not also make any explicit reference to these three issues.

In Nigeria, as in so many other developing countries, strike actions had been carried out in protest over a wide array of reasons including poor remuneration, staff welfare/job security issues, health infrastructural deficiencies, and poor quality of health services. There is still no single best answer against or in favour of doctors' strike actions [18]. Utilitarians may justify such actions on the basis of potential long-term benefits to the doctor, patient and the health care delivery systems. Others would, nevertheless, argue that under the Hippocratic-based oaths, care of the patient is mainly a social contractual obligation for the doctors and should have primacy over other considerations [18].

Regarding payment for services, some may argue that the historical rule is that a doctor is not bound to accept a patient regardless of the severity of the condition, but that it becomes ethically indefensible to do such once the contractual doctorpatient relationship is established. The demand for cash deposits in Nigerian hospitals before a patient is treated has become a dangerous trend in the health care sector [19]. The propriety or otherwise of this practice is still debatable as there is no clear legal reference point in Nigeria to compel a medical practitioner to treat a patient who is unable to pay, unlike in some jurisdictions like America which require a practitioner to accept an indigent patient for treatment, this being predicated on the principle of preserving life at whatever costs [19]. On a related note, medical students in Nigeria were shown in another study to have identified issues related to payment of medical bills as among the leading ethical challenges confronting medical doctors in Nigeria [7]. There is no doubt that this issue along with other debatable issues are changing the entire construction of medical practice and education in the country.

As a curricular event required for the professional development of these fresh medical graduates, the tradition of taking of medical oaths at formal ceremonies should be sustained by medical schools. Although all the traditional tenets and ideals espoused in these oaths continue to resonate with these junior doctors, there is a need to review the contents with a view of addressing the emerging and evolving realities of the medical environment in Nigeria, an environment that has witnessed significant social, economic, cultural and political changes. For these oaths to gain greater relevance and priority among these doctors, they should be recited within the context of a reformed, robust undergraduate medical educational system with an integrated medical ethics curriculum and a functional health care system that is responsive and sensitive to societal needs and changes.

#### References

- 1) Jotterand F. The Hippocratic Oath and contemporary Medicine: Dialectic between past ideals and present reality. *Journal of Medicine and Philosophy* 2005;30 :107-128
- 2) Meffert JJ. "I Swear!" Physician oaths and their current relevance. *Clinics in Dermatology* 2009; 27:411-415. doi:10.1016/j. *clin. dermatol.* 2009.02.016.
- 3) Newman A, Park IR. An oath for entering medical students. *Academic Medicine* 1994 Mar;69(3):214.
- 4) Kao AC, Parsi KP. Content analyses of oaths administered at U.S. medical schools in 2000. *Acad Med* 2004;79(9):882-887.
- 5) The World Medical Association. Declaration of Geneva. Geneva, Switzerland. Adopted September 1948

- and amended 1968, 1983, 1994. www.wma.net/en/30publications/10policies/g1/WM A\_DECLARATION-OF-GENEVA\_A4\_EN.pdf (accessed December 20,2016).
- 6) Abegunde B. Legal implications of ethical breaches in medical practice: Nigeria a case study. *Asian J Humanities and Social Sciences* 2013 Nov; 1(3):69-87.
- 7) Ogundiran TO. Adebamowo CA. Medical Ethics Education: A survey of opinion of medical students in a Nigerian university. *J Acad Ethics*. 2010;8(2):85-93.
- 8) Hurwitz B, Richardson R. Swearing to care: the resurgence in medical oaths. *BMJ* 1997;315:1671-1674.
- 9) Jonsen A. A short history of medical ethics. Oxford: Oxford university Press, 2000:4
- 10) Tyson P. The Hippocratic Oath today. *NOVA*. www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html. Accessed December 23,2016.
- 11) Orr RD, Pang N, Pellegrino ED, Siegler M. Use of the Hippocratic Oath :a review of twentieth century practice and a content analysis of oaths administered in medical schools in the U.S. and Canada in 1993. *J Clin Ethics* 1997; 8:377-388.
- 12) Huber SJ. The White coat ceremony: a contemporary medical ritual. *J Med ethics* 2003;29:364-366 doi:10.1136/jme. 29.6.364.
- 13) Loudon I. The Hippocratic Oath. BMJ 1994; 309:414.
- 14) Moffic HS, Bayer T, Coverdale J. The Hippocratic Oath and medical students. *Acad Med* 1990 Feb;65(2):100-101.
- 15) Stern DT. Practicing what we preach? An analysis of the curriculum of values in medical education. *Am J Med* 1998; 104: 569-575.
- 16) Yakir A, Glick SM. Medical students' attitudes to the Physician's Oath. *Med Educ* 1998; 32:135.
- 17) Perez SG, Gelpi RJ, Rancich AM. Doctor-patient sexual relationships in medical oaths. *J Med Ethics* 2006;32:702-705 doi:10.1136/jme.2005.014910
- 18) Abbasi I N. Protest of doctors: a basic human right or an ethical dilemma. *BMC Med Ethics* 2014,15:24. http://www.biomedcentral.com/1472-6939/15/24
- 19) Obidimma EOC, Obidimma AE. Legal and ethical issues in the demand for payment before treatment in Nigerian hospitals *Journal of law, policy and globalization* 2015;38:176-181.

### **Unethical Clinical Trials in India: A Selective preliminary overview**

- Ankita Chakravarty

West Bengal National University of Juridical Sciences, No.12, LB Block,

- Ambedkar Bhavan

Sector III, Salt Lake City, Kolkata, West Bengal 700098, India

### **Abstract**

This paper attempts to study the phenomena of clinical trials in India with a specific focus on the conduct of unethical trials. There has been a widespread chronicling of the rise of the great pharmaceutical power, the triumphs leading to improvements in life expectancy along with treatments and cures for numerous diseases. But there has also been the equally fascinating tale of the appalling usage of power in the form of coercion and deceit, with human beings exploited and subjugated to horrific forms of torture for the advancement of scientific knowledge and financial gains.

### 1. Introduction

There are legal and ethical provisions relating to the clinical trials sector and these provisions have been formulated both at the international and national levels and one of their major aims is to provide protection to the participants of clinical trials. However, despite the existence of a number of ethical guidelines as well as the legal stipulations, there have been numerous instances of clinical trials being conducted unethically and illegally in India. While such trials have been reported from other parts of the world as well, there have been quite a few Indian cases recently which continue to be in focus- thereby providing the basis for this research work.

India has been hailed as an emerging clinical trial location over the last decade or so and the different advantages it offers have been repeatedly highlighted (Yee 2012). Pharmaceutical companies are the major sponsors of clinical trials and as more and more of these companies venture into drug development and clinical trials, there is a need to have access to a large pool of participants for the trials. Along with the population advantages and the availability of lower cost of labour and expertise available in India, the facilities promised by the Government have also played an important role in setting up India as an attractive location. However, the reports of trials being repeatedly carried out unethically and illegally have raised certain

questions about the functioning of the clinical trials sector in India.

This study seeks to investigate the clinical trials sector in India as, over the last few years, the question of clinical trials in India has been a contentious one. This is largely because a number of trials were found to have been conducted on Indian patients without following the necessary legal and ethical principles (recently, for instance, the HPV Vaccine trial, Indore Public Hospital and Bhopal Memorial Hospital trials). It is this area within the clinical trials sector which forms the focus of this work- however, the scope of this paper is only limited to an overview of some of the earlier reports of unethical trials in India. For this purpose, the publication of the ICMR Ethical Guidelines has been taken as the integral development, and hence, only trials which were reported prior to the development of the guidelines have been included in this short review.

### 2. The ethical questions: unethical clinical trials in India

In order to gain an insight into the clinical trials sector in India, we need to try and understand the context in which it was established and the subsequent path of its development. This necessitates identifying the historical cases of unethical trials in India along with documenting the recent cases.

The cervical dysplasia trial was perhaps the first well documented case of trials being conducted in India. In 1970s and 1980s researchers at the Institute for Cytology and Preventive Oncology which is an institute under the Indian Council of Medical Research (ICMR) in New Delhi, carried out a study on women patients who presented with different stages of cervical dysplasia or what were suspected to be precancerous lesions of the cervix. The women were not informed that they were participating in a trial, and hence, none of them were asked for consent. Nonetheless, it should be noted that the researchers said that they took verbal consent from the women who were illiterate. They also argued that the study was justified in that there was 'no conclusive evidence' that all severe dysplasias develop into cancer. However, while the study was underway, a major North American medical journal published the findings of a longitudinal study of cervical cancer.

The study concluded that cervical dysplasia was indeed a precursor for cervical cancer, and thus that all forms of dysplasia were to be treated. However, despite these new findings, the Indian researchers continued with the study. The subject participants were left untreated to see how many

lesions progressed to cancer and how many regressed. By the end of the study seventy-one women had developed malignancies and lesions in nine of them had progressed to invasive cancer. Sixty-two women were treated only after they developed localised cancer. It was largely due to the controversy that erupted after the study was highlighted in the 1990s, that the ICMR Ethical Guidelines for Biomedical research in Human was formulated in 2000 (Srinivasan, 2005).

Although India adopted Schedule Y and Schedule XA of the Drugs and Cosmetics Rules 1945 which relates to clinical trials in 1988, the study highlights the ethical issues that can emerge in clinical trials, and therefore establishes why such trials need to be closely regulated. Further, the principles enshrined in the Helsinki Guidelines were not adhered to. While the investigators asserted that they had acquired verbal consent, there was no evidence that the women had been informed about their potential participation in a clinical research study. Further, despite the fact that the research published in the journal clearly established that all forms of dysplasia warranted treatment, the Indian investigators continued with the study. This is clearly not in keeping with Article 7 of the Helsinki Guidelines (1964) which establishes that 'physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits'. Further, it had been clearly stated in the introduction to the guidelines that the mission of the physician was to safeguard the health of the people.

It also needs to be clarified that in the presentation of this case as well as the other subsequent cases, the term 'subject participant (s)' is being used. What is being referred to is, the process of the constitution of the trial participant as 'subject participant' rather than merely a volunteer participant. This is especially true in case of unethical trials where the patients may not be aware of or fully comprehend their status as experimental sites. However, the intrinsic unequal power relations between the trial organizer and the participant also constitute her/him as a subject participant even if she/he is aware of the trial. The vulnerability and defenselessness of their position is more markedly revealed since it is their own resource of life which is leased out as resource matter for trial activities which are carried out to ostensibly improve life existence and yet, may paradoxically lead to diminishing of their own life existence.

The second case being presented here is from the 1990s. A huge multi-country unauthorized trial was carried out on thousands of illiterate Indian and Bangladeshi women wherein the anti- malarial compound mepacrine was used in pellet form as a means of female sterilization. Once inserted into the women's uterine cavity, it caused inflammation and scar tissue formation which closed off the fallopian tubes permanently. 15 While the trials had been stopped in the West, the compound had been directly distributed to medical practitioners in India. More than 30.000 women in India had been sterilised using this illegal and untested method, at least 10,000 in West Bengal alone. This trial demonstrates the differing ethical standards applied in different country settings. In what was clearly an illegal move, although the trials had been stopped in the west, the intervention was directly distributed to medical practitioners instead of being properly approved for testing. The Supreme Court banned the use and sale of this drug but it continued to be available in rural Bengal for up to five years after that (Dasgupta, 2005).

The M4N AND G4N trial is another important case in the account of India's clinical trial history. In 1999, 27<sup>16</sup> people with oral cancer were under treatment at the government-run Regional Cancer Centre in Thiruvananthapuram. Although there were established protocols of treatment including surgery, chemotherapy and radiation options, the patients were given first-in-human experimental drugs, tetra-0-methyl nor-dihydro-guaiaretic acid (M4N) or tetraglycinyl nor-dihydro-guaiaretic acid (G4N). The aim was to determine whether these chemicals could arrest the growth of oral cancer. Although the subject participants were made to sign consent forms, they were not informed that they were participating in a research study or that there were other approved means of treatment for their condition. While approval for the anti-cancer

<sup>&</sup>lt;sup>15</sup>Mepacrine is the name of the compound, but it was better known by its commercial name Quinacrine. Although its use in sterilization has passed through several small trials, there has been no overall dismissal of its link to cancers and ectopic pregnancy and hence, WHO convened a technical consultation which decided that Quinacrine should not be used for sterilization purposes in women, either in research or therapeutic settings. (WHO Technical Consultation, 2009)

<sup>&</sup>lt;sup>16</sup> While the questions on the ethical conduct of the trial are numerous, there also appears to be some confusion on the total number of trial participants. The RCC had initially acknowledged 27 patients but later released data on only 23 of them. Subsequently, only 18 cases were taken into account.

drug trial was taken from the Indian drug regulator only after the trial was underway (Srinivasan, 2005), ethical clearance from the collaborating organization- John Hopkins University had also not been provided.

The trial was only thrust into the media spotlight after a radiotherapist from the centre raised serious questions on the conduct of the trial. While there was an enquiry established in India as well as in the US, only 'procedural lapses' were found to have occurred. However, it must be noted that the University barred the principal investigator from conducting any further research on the chemical entities and also provided that any further human clinical research to be carried out by the investigator would have to be supervised by someone from the University who had experience in dealing with human trials (Frontline, Vol.22 Dec. 2005). Subsequently, animal testing was done on these chemicals before the launch of Phase 1 trials on humans in USA. Moreover, the volunteers in the US trial were patients who did not have any therapy option available to them. This was not the case with the Indian subject participants. This particular trial also serves to highlight the reprehensible process in which trials are organized in India. Firstly, the subject participants were not informed that they were participating in a clinical trial, and thereby receiving experimental therapy as opposed to approved therapy, thereby effectively amounting to denying them treatment.

Moreover, the trial was initiated before permission was sought, which was illegal as per Section 1.2 of Schedule Y of the Drugs and Cosmetics Act, 1945 (GSR 944 (E) 1988). Further, the ethical committee clearance of the collaborating body should also have been obtained as no such clearance had been acquired. It may be pertinent to point out that one of the possible reasons for the ethical clearance not being sought from John Hopkins University, might have been that it would have been unlikely that permission would have been granted because of the serious ethical question on the study itself. Hence, the question cannot be looked at in isolation- what also needs to be focussed upon is the undeniable role of the context of such a trial. This refers to the fact that the trial was being carried out in a third world nation-state which has a history of poor regulatory oversight; also the lack of ethical clearance from the US (first world) makes it an intriguing case and raises the pertinent question of elitism and even, worryingly, racism.

These three trials are illustrative cases of the nature and extent of unethical as well as illegal practices that are widely prevalent in the pursuit of clinical research in India. To state clearly, all of

these studies violated the four basic tenets of ethics as per the ICMR Ethical Guidelines- autonomy (respect for person /participant), beneficence (act for the benefit of person/participant), non-maleficence (do no harm) and justice (ICMR Ethical Guidelines). Subjects were not informed that they were participating in clinical research and actual informed consent was not taken. Participants were subjected to the trials while being deliberately deceived that they were receiving standardized therapy as opposed to experimental interventions.

The three cases of unethical trials that were presented- the cervical dysplasia trial, the mepacrine pellet trial and the G4N & M4N trials were all conducted before the ICMR Ethical Guidelines for Biomedical research in Human Subjects was presented in 2000, although the 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' had in fact, been published in 1980. The ICMR Ethical Guidelines for Biomedical research in Human were published first in 2000 while the CDSCO prepared the Indian Good Clinical Practice (GCP) guidelines in 2001. It is to be expected that after the categorical formulation of ethical and clinical considerations necessary for conducting clinical research in India, the situation would be somewhat different.

However, reports over the last few years have not been positive and instead brought to light further examples of unethical conduct of clinical trials. However, that is beyond the scope of this paper.

### 3. References

Dasgupta,R. (2005)'Quinacrine Sterilization in India: Women's Health and Medical Ethics Still at Risk 'http://www.global-sisterhood-

network.org/content/view/237/59/

Krishnakumar, R. 'Trial and Errors' *Frontline*, Volume 22 - Issue 25, Dec. 03 - 16, 2005 http://www.hindu.com/thehindu/thscrip/print.pl?file =20051216005102200.htm&date=fl2225/&prd=fline &

ICMR Ethical Guidelines, 2006

Helsinki Guidelines, WMA, 1964

Srinivasan, S. (2005) 'Some Questionable trials' http://infochangeindia.org/public-

health/features/some-questionable-drug-trials.html

WHO Technical Consultation (2009) http://whqlibdoc.who.int/hq/2009/WHO\_RHR\_09.21\_eng.pdf

Yee, A. (2012) 'Regulation failing to keep up with India's trial boom'. *The Lancet*, Volume 379, Issue 9814, Pages 397 – 398.

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