

Global Bioethics Enquiry

The Scholarly Publication of the UNESCO Chair in Bioethics



Volume 7, Issue 3
DECEMBER 2019

The scholarly publication of the UNESCO chair of Bioethics

GLOBAL BIOETHICS ENQUIRY

Issue 7 (3)

December 2019



Editorial Board

EDITOR-IN-CHIEF

Prof. Dr. Russell D'Souza (Australia)

EDITORS

Prof. Dr. Mary Mathew (India)

Prof. Eleanor Flynn (Australia)

Prof. Baroness Ilona Finlay (UK)

Prof. Dr. Harischandra Gambheera (Sri Lanka)

MANAGING & ASSOCIATE EDITOR

Prof. Dr. Avinash De Sousa (India)

EDITORIAL BOARD

Prof. Dr. E. Mohandas (India)

Prof. Dr. Derek D'Souza (India)

Prof. Dr. O.P. Kalra (India)

Prof. Dr. Bipin Batra (India)

Prof. Dr. Bhabatosh Biswas (India)

Prof. Dr. Abey Gaidhane (India)

Prof. Dr. Barna Ganguly (India)

Prof. Dr. Princy Palatty (India)

Prof. Dr. Smita Deshpande (India)

Prof. Dr. Anu Kant Mital (India)

Prof. Dr. Prasanta Mitra (India)

Prof. Dr. Srikanth Nimmgadda (UK)

Prof. Dr. Anand Ramakrishnan (UK)

Prof. Dr. Rajiv Tandon (USA)

Prof. Toshiko Sawaguchi (Japan)

Prof. Hongjie Man (China)

Prof. Dr. Eva Avlogari (Greece)

Prof. Shai Linn (Israel)

Prof. Vojin Rakic (Serbia)

Prof. Altin Stafa (Albania)

Prof. Mariela Deliverska (Bulgaria)

Prof. Marian Mutugi (Kenya)

Prof. Henry Coudane (France)

Prof. Gabriele Werner-Felmayer (Austria)

Prof. Veronique Delpire (Belgium)

Prof. Tatjana Poplazarova (Belgium)

Prof. Ashima Khan (Pakistan)

Prof. Dr. Shabbir Amanullah (Canada)

TABLE OF CONTENTS

Contents	Page Number
Editorial Gender variant patients with psychiatric illnesses: Health care barriers, treatment challenges and ethical dilemmas <i>Pragya Lodha, Avinash De Sousa, Russell D'Souza</i>	113–117
Review Paper Holistic Approach to The Environment and GMOs – The Case of Golden Rice <i>Ivica Kelam</i>	118–127
Review Paper Ethical concerns in Animal Cloning: Possible Risks and Assessment <i>Neha Sinha, Sharvil Patil, Udaya Kesigan, T. Sai Chaitanya, Simran Panigrahy, G.D. Tandon</i>	128–135
Review Paper Inclusion of Bioethics in Performance Appraisal for Promoting Ethical Behaviour among Doctors in Hospital <i>Deepak Singla, Bharathi Saxena, Amit Mahajan</i>	136–140
Original Research Paper Awareness of Patient's Rights Amongst the Teaching Faculty of Non-Medical Teaching Institutions in Belagavi <i>Rinku Porwal, Vishal Koulapur, Somshekhar Pujar, Girish Moogi, Kiran Patil, Premalata Rotti</i>	141–145
Original Research Paper A Study to Assess the Awareness of Justice, Equality and Equity -Amongst Homeopathic Practitioners in Practice <i>Premalata Rotti, Kiran Patil, Girish Moogi, Rinku Porwal</i>	146–150
Student Essay Respect For Cultural Diversity <i>Sujata Devi</i>	151–152
Student Essay Respect For Cultural Diversity <i>Rashmita Devi</i>	153–154
Student Essay Respect for Cultural Diversity <i>Ibajoplin Mary Kharkongor</i>	155–156
Ethical Viewpoint Paper Ethical Issues in the Beginning of Life <i>Padmaja Kanchi, Subodh Kanchi</i>	157–159

Ethical Viewpoint Paper Ethics in Radiology <i>Khalid Ahmad</i>	160–164
Scope of the Journal and Instructions to Authors	165–169

Editorial

Gender variant patients with psychiatric illnesses: Health care barriers, treatment challenges and ethical dilemmas

Pragya Lodha¹, Avinash De Sousa², Russell D'Souza³

¹Clinical Psychologist and Research Associate, DeSousa Foundation, Mumbai.

²Research Associate, Department of Psychiatry, Lokmanya Tilak Municipal Medical College, Mumbai.

³Director and Head, Asia-Pacific UNESCO Chair in Bioethics, Haifa.

Corresponding Author: Avinash De Sousa

E-mail: avinashdes888@gmail.com

Gender variance is an umbrella term describing behaviours, interests, appearance, expression, or an identity of persons who do not conform to culturally defined norms expected of their natal gender [1]. There are additional experiences of discomfort with their biological sex, primary and secondary sex characteristics and social gender roles. Resultantly, they experience various levels of distress, from depressive moods, anxiety, low self-esteem, lack of confidence, intra-psychical conflicts to suicidal ideation and psychotic breakdowns. The last decade has witnessed a significant rise in gender variant persons looking for care at gender clinics across the world. The LGBTQ+ population is also referred to as gender variant persons. Increasing psycho-social awareness, socio-political initiatives in support, social media empowerment, globalisation through the information world, greater receptivity by the family members and peers with regard to one's gender identity crisis and media appearances of LGBTQ+ individuals have encouraged a lot of individuals to come out about their sexuality.

In accordance, some individuals may choose to undergo 'transition' in order to comply with the gender they (psycho-socially) identify with. Transitioning is a process of changing one's gender presentation in order to align it with their internal sense of gender identity. Transitioning may happen *socially*, which may involve using a different name, pronouns, transformation of physical appearance, use of suitable bathrooms, and taking social roles of the affirmed gender. However, transitioning may also be *medical* where the individual may choose to undergo hormonal and medical surgeries. More transitions happen from male to female (MTF) than from female to male (FTM)- transgenders are MTF transsexuals [2].

The challenge of accessing mental health care for the LGBTQ+ community has remained as a doubled edged sword given their non-conforming gender identities and stigma towards mental health. The incidence of mental health problems among the LGBTQ+ is noted to be 2-3 folds higher than their heterosexual counterparts. Within the gender variance, there are some sub-populations that face greater challenges than the other. Lesbians and transgender communities are said to face 2-fold greater risk for mental health problems within the community [3]. Some of the common mental health problems seen among the LGBTQ+ persons are: depression, anxiety, suicidality, post-traumatic stress disorder, bipolar disorder, schizophrenia, obsessive compulsive disorder, panic disorder, eating disorder.

Additional socio-cultural barriers present as low self-esteem, low confidence, body image issues, social ostracization, homelessness, forced prostitution, poverty and interpersonal relationship violence [4]. Formulation of public health policies directed to the group, implications of gender issues, the structuring of health services, and performance of professionals, directly interfere with access of and guarantee the right to health of the LGBTQ+ population [5]. Though the governments have taken some active steps for the wellbeing for the community, the similar fails to reflect in implementation and the discriminatory divide persists. There are various challenges that

exist and the present article shall discern the health-related barriers, treatment challenges and ethical dilemmas.

Health-care barriers

One of the greatest barriers that LGBTQ+ people experience in accessing mental health care is the anticipation of and experience of discrimination. Some disquieting barriers [6] in mental health care, faced by gender variants person are as enlisted:

1. Several mental health professionals lack knowledge about the sexual orientation of the person. Either, sexual orientation is disregarded because of which the approach to healthcare becomes unsatisfactory from the perspective of patient-needs; or, patients are asked to 'explain (educate)' the professionals about their non-conforming orientation. In such cases, it is not uncommon for patients to feel uncomfortable and they report to feel 'not understood'. It is not the best practice to have patients educate professionals about some fundamental parameters which are indicated as a must-know for professionals.
2. Often transgender patients become a specimen sample for doctors, creating grounds of ridicule and disregard for the patient. It has been documented in newspaper reports how doctors use trans patients to show their residents about 'what and how do trans people look like'; appalling to learn that trans patients are often asked to undress for this purpose of teaching the students. This not only dwindles the health care access for trans patients but is also an outright violation of patient and human rights.
3. For trans patients, there is ridicule right from the gate of the hospital to the clinic of the doctor. Given their appearance is stark, they are often subject to derision by peons and sometimes asked to return from the gate of the hospital.
4. Policy provisions fail to issue anti-discriminatory health policies for the inclusive benefits of gender variant persons. Paradoxically, though they have fundamental constitutional rights, they fail to receive the benefit of the health care services.
5. Till today, a majority of the mental health care professionals do not have an understanding of the problems of the gender-variant population as a consequence to their homophobic and transphobic attitudes. Most mental health professionals either belittle the problems, may have belligerent attitudes towards patients or may categorically deny treatment. Additionally, it is saddening to encounter that several health professionals continue to believe homosexuality as an illness.
6. Lack of trained and specialised mental health professionals in the LGBTQ+ health concerns is a further challenge for addressing their issues. Several patients feel they are not welcomingly understood by professionals and this gap in rapport building impedes further treatment outcomes.
7. Family non-acceptance, bullying by peers and ostracization by the heteronormative society adds to the struggle for healthcare access and seeking such services for gender variant individuals. As a society that supposedly is increasingly progressive and inclusive, we still lag to see the cultural competence that can disable the existing stigma towards gender non-binaries.
8. Lastly, there is still lack of data when it comes to accounting for records and health trends among the LGBTQ+ population. Especially so, the dearth of literature is lesser in developing countries like India.

Treatment Challenges and Ethical Dilemmas

Among the several disabling mental health conditions, one of the challenges faced by the LGBTQ+ population is gender dysphoria. Gender dysphoria (GD) has replaced the diagnosis of Gender Identity Disorder. GD represents a condition where a person's gender assigned at birth and the gender with which they identify themselves are incongruent. It is a condition where the individual experiences dysphoria (persistent low mood) because of this incongruence. Prevalence rate cannot be correctly estimated considering that people are still hesitant to come forward to health centres. According to DSM-5, the prevalence of gender dysphoria is 0.005-0.014% for adult

natal males and 0.002-0.003% for adult natal females [7] There is paucity of scientific data from India on gender dysphoria.

Ethical principles in bio-medical practice are autonomy, beneficence, nonmaleficence, and informed consent. The individual must have autonomy of thought and intention when making decisions about medical treatment. This is an especially sensitive field in treatment of gender dysphoria, because sometimes the individual's desires, hopes, and expectations might not correlate with reality.

Experts must be very straightforward and transparent regarding specific possibilities, risks, and benefits of medical treatment, especially considering that the last step in medical transition, GAS, is irreversible. Beneficence implies doing only good, only what is in the patient's best interest. Nonmaleficence must ensure that the treatment does not harm the individual in an emotional, social, or physical sense. It seems that, even with the reassurance and recommendation from a mental health professional, ethical unease cannot be entirely erased.

One of the fundamental challenges with treating GD is that despite the diagnostic revision and several efforts taken to create awareness around the phenomenon, gender dysphoria continues to remain misunderstood, underdiagnosed and misdiagnosed. Further, lack of specialised professionals in queer mental health and prevalent homophobia among mental health professionals has deterred and delayed treatment for many.

With recognised rights and access to health care services, there has been a surge in adolescents seeking for gender affirmation surgeries and hormone replacement treatments to do away with the distress. Such a medical treatment is a sensitive one involving a liaison among experienced mental health professionals, endocrinologists, and surgeons.

The seventh edition of the Standards of Care of the World Professional Association of Transgender Health (WPATH) offers flexible guidelines for the treatment of people experiencing gender dysphoria and describes the criteria for surgical treatment [8]. However, many countries including India do not have such care-bound guidelines. Psychiatric assessment is the first and very complex step before undergoing any medical surgery. Psychiatric assessment involves an in-depth history taking along with adequate psychological testing administered, to rule out psychiatric conditions that might mimic gender dysphoria. Often, psychotic presentations (schizophrenia, psychotic depression, brief psychotic disorder) are found to mimic GD.

The next in process is hormonal treatment which is governed under the care of an endocrinologist, which is then followed by "a real-life trial." Some individuals decide to stop here, while others continue to gender-affirming surgery (GAS). Gender affirmation surgery refers to all surgical procedures that a patient wishes to undergo in an attempt to become as similar as possible to the desired gender.

Children with Gender Dysphoria

Typically, 10-20% children continue to live with gender dysphoria and most children return to their natal genders (process referred to as 'desisting'). The challenges is typically with those children whose gender dysphoria translates into their adolescence; such individuals are more likely to experience gender dysphoria as adults as well. As part of procedural protocol, no GAS can be undertaken without confirming through psychiatric assessment that elements of psychosis and / or other interfering psychiatric comorbidities has been ruled out. Further, counselling sessions prior to the surgery must help in establishing a psycho-social readiness for the patient before they permanently transform to another gender orientation and identity. More often than not, often this readiness may not be long-lasting and may find incongruence in post-surgery counselling.

Paediatric patients are unable to make decisions with autonomous, independent informed consent for medical treatments. This protects children who often do not possess fully developed cognitive decision-making capacity by preventing rash, permanent, and potentially regrettable medical decisions. Until adolescents reach age of majority, the decision making remains with parents. However, increasingly, there has been a surge in the younger population demanding for GAS owing to liberal awareness. One of the preferred treatments for underage population is to treat them with gonadotropin-releasing-hormone that delays puberty, prevents development of secondary sexual characteristics and thus helps to buy time to consider next stages of therapy.

Another treatment option is to allow cross-sex hormone therapy (androgens for natal females and oestrogens for natal males) and GAS at reaching age majority. Puberty suppression using gonadotropin-releasing-hormone analogues has become increasingly accepted as an intervention during the early stages of puberty in individuals with clear signs of childhood-onset gender dysphoria. However, lowering the age threshold for using medical intervention for children with gender dysphoria is still a matter of contention, and is more controversial than treating the condition in adolescents and adults, as children with gender dysphoria are more likely to express an unstable pattern of gender variance. Furthermore, concerns have been expressed regarding the risks of puberty suppression, which are poorly understood, and the child's ability to make decisions and provide informed consent [9].

Parental hesitance is common when the child demands to get a sex-reassignment surgery done. For a parent who has always been used to see their child, address them and identify them as their natal gender, it can be an arduous deal to see them as another (opposite) gender [10]. Many parents find it more accepting to have their children come out as homosexual in orientation however, it is far more distressing for them to come to terms with their children pursuing to undergo GAS. The similar is aggravated with societally prevalent transphobic attitudes. Considering the patient rights and non-binary gender approaches forming a crucial element in treatment processes, it is imperative that parents choose the well-being of children.

Literature has reported individuals who are allowed to conform to their psychological gender are found to have correlates with positive mental health (emotional well-being, emotional stability and overall health) than their counterparts [11]. A lot of them come to terms with their inability to procreate however some of them do grieve their infertility [12]. A lot of families fail to integrate transsexual / transgender individuals which leads to homelessness among these individuals.

Many parents bring children presenting with gender variance to mental health professionals with a request to counsel the child or medicate them in order to maintain heteronormativity. There is a percentage of mental health professionals who do engage in talk therapy and electroconvulsive therapy with a guarantee to 'change' their homosexual / trans orientation and identity. Such procedures only aggravate mental health conditions among the individuals. On the other hand, queer friendly mental health practitioners find it a strenuous task to make parents understand the normalcy of their children not wanting to identify with heteronormative cultural identities.

Conclusions

Regardless of independent conclusions from research studies and individuals, there is a need for additional research into gender identity development into the long-term safety of cross-sex hormone therapy is imperative. It is imperative that all ethical analysis must acutely consider the age and cognitive development of the person with gender dysphoria. While long-term safety and reversibility of puberty-suppressing hormones make the first-stage treatment justifiable for many assenting children, the second-stage treatment of cross-sex hormones—with the long-term fertility implications—are generally justifiable only with adolescents that can provide fully informed assent. No treatment comes with complete satisfaction and without risk, thus, the pros and cons must be weighed in the context of individual concerns and needs.

REFERENCES

1. Coleman EB, Bockting WO, Botzer M, Cohen-Kettenis P, DeCuypere G, Feldman J. Standards of care for the health of transsexual, transgender and gender non-conforming people, version 6. *Int J Transgend* 2001;17:366–433.
2. Paul J. Under the Radar: Exploring Support for Lesbian, Gay, Bisexual, Transgender, Queer and Questioning (LGBTQ) Youth Transitioning from Foster Care to Emerging Adulthood. The University of Wisconsin-Madison; 2018.
3. Gnan GH, Rahman Q, Ussher G, Baker D, West E, Rimes KA. General and LGBTQ-specific factors associated with mental health and suicide risk among LGBTQ students. *J Youth Stud* 2019;14:1-6.
4. Snapp SD, Watson RJ, Russell ST, Diaz RM, Ryan C. Social support networks for LGBT young adults: Low cost strategies for positive adjustment. *Fam Relat* 2015;64(3):420-30.

5. Klein DA, Berry-Bibee EN, Baker KK, Malcolm NM, Rollison JM, Frederiksen BN. Providing quality family planning services to LGBTQIA individuals: a systematic review. *Contraception* 2018;97(5):378-91.
6. Quinn GP, Sutton SK, Winfield B, Breen S, Canales J, Shetty G, Sehovic I, Green BL, Schabath MB. Lesbian, gay, bisexual, transgender, queer/questioning (LGBTQ) perceptions and health care experiences. *J Gay Lesbian Soc Serv* 2015;27(2):246-61.
7. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 4th. Vol. 1. Arlington, Va, USA: American Psychiatric Association; 2000.
8. Coleman E., Bockting W., Botzer M. Standards of care for the health of transsexual, transgender, and gender nonconforming people, version 7. *Int J Transgenderism* 2012;1:165–232.
9. Costa R, Carmichael P, Colizzi M. To treat or not to treat: puberty suppression in childhood-onset gender dysphoria. *Nat Rev Urol* 2016;13(8):456-62.
10. Rachlin K, Green J, Lombardi E. Utilization of health care among female-to-male transgender individuals in the United States. *J Homosexuality* 2008;54(3):243-58.
11. Colton Meier SL, Fitzgerald KM, Pardo ST, Babcock J. The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *J Gay Lesb Ment Health* 2011;15(3):281-99.
12. Abel BS. Hormone treatment of children and adolescents with gender dysphoria: an ethical analysis. *Hastings Center Report* 2014;44(s4):S23-7.

Acknowledgements – Nil

Source of Funding – Nil

Conflict of Interest – Nil

Review Paper

Holistic Approach to The Environment and GMOs – The Case of Golden Rice

Ivica Kelam¹

¹Assistant Professor at Faculty of Education/Josip Juraj Strossmayer University of Osijek, Croatia; Head of the Croatia Osijek Unit of UNESCO Chair in Bioethics (Haifa); Head of the Centre of Integrative Bioethics at Josip Juraj Strossmayer University of Osijek; Head of the Department of Philosophy and History/Faculty of Education.

Corresponding Author: Ivica Kelam

E-mail: kelamivica@gmail.com

ABSTRACT

This paper aims to point out the fundamental differences between supporters and opponents of genetic modification technology by using a brief analysis of the development and controversy that surrounds the genetically modified golden rice. Supporters present golden rice like a typical example of the benefits of genetic modification technology and, at the same time, accuse opponents of delaying commercial planting. Opponents from the very beginning point to the problem of golden rice as a partial quick fix of vitamin A deficiency, whereby the complexity of the problem of vitamin A deficiency in the diet of the population of underdeveloped countries is ignored. Today, 19 years after the presentation of golden rice in the media, this technology is still not ready for commercial use, not because of opposition by Greenpeace and other opponents, but because of the elementary fact that introducing genetically modified plants into a living environment is a challenge that science cannot yet adequately respond. In this paper on the golden rice example, we will point out the importance of the holistic approach to the environment taking in a count the complexity and unpredictability of introducing new biotechnological inventions into the environment

Keywords: Biotech industry, golden rice, Greenpeace, vitamin A deficiency, environment.

INTRODUCTION

For the development and successful implementation of genetically modified crops, public support is one of the critical elements. From the very beginning, sowing genetically modified crops has caused controversy in public, golden rice has presented in addition to its health properties as an example of the benefits and usefulness of genetic modification technology. Environmental NGOs like Greenpeace argue that golden rice is not a solution to the problem of vitamin A deficiency, but a means of imposing unwanted technology on the suspicious public. The saga about golden rice has lasted for 19 years, and during that period there have been exchanged serious accusations between opponents and supporters, ranging from the introduction of corporate dictatorship by opponents to supporter's accusations of the Holocaust for preventing the introduction of golden rice into the diet. In the paper, through a brief analysis of the history of development and controversy over golden rice, particular emphasis will be placed on the lack of research into the

environmental and social impact of golden rice, from which it is evident that, despite its noble intention, it remains only an unfulfilled dream of its creators.

Golden rice - a brief overview of development and some ethical issues

Ingo Potrykus, a professor at the Swiss Federal Institute of Technology, appeared on the cover of Time Magazine with the headline 'This rice could save a million children a year' [1]. The article describes Potrykus' creation of genetically modified rice enriched with carotene, which he claims could save children in undeveloped countries from blindness and death. The Golden Rice project started back in the 1980s. In August 2012, Greenpeace issued a press release informing the public of a study published in a scientific journal describing the experiment of feeding genetically modified rice to 24 Chinese children between the ages of 6 and 8 [2]. Greenpeace argued that the said study, supported by the United States Department of Agriculture, could not have been conducted without violating the postulates of scientific and medical ethics. A Greenpeace spokesman for East Asia, responding to this news, said: 'It is incredibly disturbing to think that the US research body used Chinese children as guinea pigs for genetically modified food, despite a clear directive against this experiment issued by Chinese authorities in 2008' [2].

A controversial study, *β-Carotene in Golden Rice is as good as b-carotene in oil at providing vitamin A to children* referenced by Greenpeace evaluated the efficacy of bio-conversion of β-carotene to vitamin A in children who were fed golden rice [3]. The paper detailed that research groups from Tufts University led by Tang, the Chinese Center for Disease Control and Prevention, and other scientific research institutions selected 72 healthy 6–8 year-old children in Hunan, China; divided them into three groups; and provided 24 children with 60 g of Golden Rice for 21 days while drawing their blood to measure the vitamin A concentrations. The results showed that the effect of the Golden Rice was as good as that of vitamin A capsules. So far this was the only scientific study conducted to determine the impact of consumption of gold rice on human health, which is why it was so media-covered and used as a key argument about the justification of the whole golden rice project. Golden rice promoters used this study for media purposes, constantly emphasizing the justification for introducing golden rice to the fields as quickly as possible. However, after three years, on July 29, 2015, the publisher unexpectedly withdrew the article, stating ethical reasons [4].

The Yu and Li addressed this problem in their paper *Informed Consent and Ethical Review in Chinese Human Experimentation: Reflections on the 'Golden Rice Event'*, according to them, Tang et al. did not provide sufficient evidence that a local ethics committee approved the study in China in a manner that is entirely consistent with the guidelines of the National Institutes of Health. Moreover, Yu and Li claim that the project also concealed from the Chinese ethics committee and the informed consent process the fact that genetically modified rice was to be used in the trial, which violated the ethical review requirements [5]. Violations of ethical principles and lack of informed consent have also been highlighted in an article published in *Nature* where it stated, none of the children, their parents or school teachers were aware that Golden Rice was involved, according to a 45-minute investigative news program broadcast on 8 December on CCTV, China's state television channel. The informed-consent form said that the rice contained β-carotene, but not that it was genetically modified or that it was Golden Rice. Nor did it highlight uncertainty around any potential risks of ingesting such rice...

Moreover, Wang didn't apply for ethical evaluation of the trial, instead fabricating the approval documents, according to CDC. And Tang brought Golden Rice from the United States to China illegally, without due declaration to the relevant Chinese authorities [6].

As is evident from this affair, the key problem is not a question of safety of human consumption of golden rice, but the lack of transparency and informed consent of all participants, including children and their parents, who have not been informed at all that their children will be consuming genetically modified golden rice. This affair has taught us that it is critical in any future studies to pay close attention to strict adherence to ethical guidelines and to obtain informed consent from

all participants. Following the withdrawal of the study, in June 2016, a group of 107 Nobel laureates in an open letter published in major world newspaper such as *The Washington Post* blamed opponents of GMOs, most notably Greenpeace, for the deaths of millions of children and adults in developing countries around the world [6]. The petition has attracted a great deal of public attention, as biotechnology promoters have used this open letter to attempt once again to impose on the public the necessity of implementing genetically modified crops as quickly as possible.

Wilhelmina Peregrine, campaigner at Greenpeace Southeast Asia in response to this open letter highlights the following: „Accusations that anyone is blocking genetically engineered ‘Golden’ rice are false. ‘Golden’ rice has failed as a solution and is not currently available for sale, even after more than 20 years of research. As admitted by the International Rice Research Institute, it has not been proven actually to address Vitamin A Deficiency. So, to be clear, we are talking about something that does not even exist. Corporations are overhyping ‘Golden’ Rice to pave the way for global approval of other more profitable genetically engineered crops. This costly experiment has failed to produce results for the last 20 years and diverted attention from methods that already work. Rather than invest in this overpriced public relations exercise, we need to address malnutrition through a more diverse diet, equitable access to food and eco-agriculture” [6].

To understand the controversy over golden rice, we need to look at some facts. More than half of the world's population eats rice daily since rice is the basis of their daily diet. Rice is a poor source of many essential micro-elements and vitamins. In Southeast Asia, 70% of children under the age of 5 suffer from vitamin A deficiency, leading to increased susceptibility to various diseases and vision problems, which in severe cases leads to blindness. According to UNICEF forecasts, increasing dietary intake of Vitamin A could prevent the premature death of between 1 and 2 million children between the ages of 1 and 4 years [7]. Proponents argue that there is no alternative to golden rice to combat vitamin A deficiency and blame government agencies and critics for endangering the lives of millions of children, like the appeal of Adrian Dubock who calculated that 50,000 children become blind every month due to the delay in bringing golden rice on the market [8]. Other proponents claim that the government agencies and NGOs are participants in the Holocaust against the underprivileged children of the global South [9]. Furthermore, to accelerate the marketing of golden rice and reduce development costs, proponents require a general reduction in risk assessment standards for genetically modified plants [10].

For delaying the commencement of commercial planting of golden rice proponents held accountable excessive state regulation and a relentless campaign of anti-GMO activists and organizations such as Greenpeace. Bjørn Lomborg, author of the book *The Skeptical Environmentalists*, wrote an article on February 2013 stating that the commercial sowing of golden rice has been delayed for 12 years because of relentless opposition to GM foods by rich, well-meaning residents of the global in the West, while around 8 million children worldwide died of vitamin A deficiency [11]. Lomborg wants to exert pressure on the public and regulatory agencies to extricate the uncontrolled introduction of genetically modified crops into the fields by overstating the deaths of children due to vitamin A deficiency. Lomborg forgets the elemental biological fact, as pointed out in a *Science* article, which points out that the long way “lies before the commercial sowing of golden rice, in the process of crossing golden rice with Indica rice varieties, which are most popular among farmers and consumers across Asia [12]. Golden rice critics such as nutritionist Marion Nestle, on the other hand, state: „This rice, although not yet available commercially, has become the poster child of the food biotechnology industry's extensive public relations campaign to convince the public that the benefits of genetically engineered agricultural products outweigh any safety, environmental, or social risks they might pose.

National magazines promote golden rice as a means to prevent the more than one million annual deaths and cases of blindness that occur among children in developing countries as a result of vitamin A deficiency. The creation of golden rice appears to confirm the belief that biotechnology is the key to solving world food and nutrition problems. Consideration of basic principles of nutrition suggests that rice containing β -carotene is unlikely to alleviate vitamin A deficiency.

To begin with, the bioavailability of β -carotene is quite low-10% or less by some estimates. To be active, β -carotene--a pro-vitamin--must be split by an enzyme in the intestinal mucosa or liver into two molecules of vitamin A. Like vitamin A, the pro-vitamin is fat-soluble and requires dietary fat for absorption. Thus, digestion, absorption, and transport of β -carotene require a functional digestive tract, adequate protein and fat stores, and adequate energy, protein, and fat in the diet. Many children exhibiting symptoms of vitamin A deficiency, however, suffer from generalized protein-energy malnutrition and intestinal infections that interfere with the absorption of β -carotene or its conversion to vitamin A. The complexity of the physiological, nutritional, and cultural factors that affect vitamin A status suggest that no single-nutrient added to food can be effective as a remedy for dietary deficiencies. Instead, a combination of supplementation, fortification, and dietary approaches is likely to be needed, along with a substantial commitment to improving socioeconomic status. Food biotechnology may yet lead to products that improve nutrition and health, but at the moment, its benefits remain theoretical [13].

Vandana Shiva argues that golden rice is not a solution to the problem of vitamin A deficiency since the first generation of golden rice contains an insufficient amount of vitamin A. Recommended daily dose of vitamin A for an adult to be obtained, according to Vandana Shiva's calculation, should eat 2,272 kilos of dry rice daily, which is, of course, impossible to achieve. According to her, the solution is not to genetically modify rice, but to allow people to diversify their diet, since many plants that grow in these parts of the world have a much higher percentage of vitamin A in them. Bengal women use more than 200 species of different plants in their diet, and more than 3 million people in Bangladesh, thanks to growing vitamin A-rich vegetables in their garden, have eliminated the risk of blindness [14]. Peter Rosset argues that golden rice does not solve the problem of vitamin A deficiency: 'If one reflects upon patterns of development and nutrition one must quickly realize that Vitamin A deficiency is not best characterized as a problem, but rather as a *symptom*, a warning sign if you will'. It warns us of broader dietary inadequacies associated with both poverty and with the agricultural change from diverse cropping systems toward rice monoculture. People do not present with Vitamin A deficiency because rice contains too little Vitamin A or beta-carotene, but rather because their diet has been reduced to rice and almost nothing else, and they suffer many other dietary illnesses that cannot be addressed by beta-carotene, but which *could* be addressed, together with Vitamin A deficiency, by a more varied diet. A magic-bullet solution which places beta-carotene into rice-with potential health and ecological hazards-while leaving poverty, poor diets, and extensive monoculture intact, is unlikely to make any durable contribution to well-being [15].

Scientific studies have shown that the prevalence of vitamin A deficiency in underdeveloped countries has decreased significantly over time, as the following data show. In 1991, 39% of children aged 6–59 months in low-income and middle-income countries were vitamin A deficient. In 2013, the prevalence of deficiency was 29%. Vitamin A deficiency significantly declined in the east, and southeast Asia and Oceania from 42% to 6%, a decline in Latin America and the Caribbean from 21% to 11% also occurred. In 2013, the prevalence of deficiency was highest in sub-Saharan Africa 48%, and South Asia 44%, 94, 500 deaths from diarrhea and 11, 200 deaths from measles were attributable to vitamin A deficiency in 2013, which accounted for 7% of all deaths in children younger than five years in low income and middle-income countries. More than 95% of these deaths occurred in sub-Saharan Africa and South Asia [16]. On the other hand, golden rice proponents, deny Vandana Shiva's allegations, pointing out that the new generation of golden rice contains a much higher concentration of beta-carotene, and, according to calculations, the daily consumption of one bowl of golden rice per person would significantly reduce vitamin A deficiency [17].

According to Swamy, the second generation of golden rice event GR2E could produce enough beta-carotene, or pro-vitamin A, to help those who suffer from vitamin A deficiency. According to the study "Mean pro-vitamin A concentrations in milled rice of GR2E [golden rice] can contribute up to 89-113 percent and 57-99 percent of the estimated average requirement for vitamin A for preschool children in Bangladesh and the Philippines, respectively" [18]. Although the

findings of this study look impressive, when analyzing the paper, it turns out that when they harvested the golden rice, the researchers then froze the grain until it was tested for its pro-vitamin A levels. They did not store it under normal conditions or cook it — two fundamental things that ordinarily happen to rice when it is marketed and consumed. That is very important to keep in mind because as Bollinedi and group points out in another recent study, storage massively reduces the beta carotene (or pro-vitamin A) content of golden rice. They showed that after just six months of storage in the presence of air, even at the low refrigerated temperature of 4 degrees C, the beta-carotene degraded by around 68–79%. Moreover, normally, rice would not, of course, be stored at 4 degrees C, let alone frozen. Cooking also degraded the beta-carotene by up to 24% [19]. They concluded that the best way to preserve the beta-carotene content of the GM golden rice was to vacuum pack it as paddy (though no one eats paddy). Under these conditions, at 25 degrees C, just over half (54%) of the beta-carotene was retained, versus only around 20% under non-vacuum packaging (air packaging) at the same temperature [19].

Swamy and his group are aware of this issue, and point out in the conclusion of their study, 'Practically, nutritional effects will be significantly influenced by substitution rates of conventional rice with rice containing event GR2E, varietal (background germplasm) effects on provitamin A expression, actual bioconversion efficiency in target populations, and the known loss of β -carotene over time due to storage, processing, and cooking methods' [18]. As can be seen from the studies cited, there are still many obstacles to commercial sowing and the successful consumption of golden rice. The problem of declining beta-carotene in golden rice confirms once again the doubts of opponents of golden rice. Moreover, the US Food and Drug Administration's recommended daily allowance of vitamin A for an adult woman is 700 μ g (micrograms), and for an adult man is even more 900 μ g [20]. According to FDA recommendations, adult men should eat 175 grams of golden rice daily. Ultimately, this means they should be overeating golden rice to meet their daily allowance of vitamin A. I will end this chapter with an interesting 2018 FDA opinion.

The US Food and Drug Administration (FDA) concluded its consultation process on GM golden rice by informing its current developers, the International Rice Research Institute (IRRI) that the concentration of β -carotene in GR2E rice is too low to warrant a nutrient content claim [21].

Examples of potentially harmful effects of relations environment-golden rice:

1. Lower yield issue

Despite the increased concentration of beta-carotene in new generations of golden rice, it should be noted that after more than 25 years of research and tens of millions of dollars spent on development, golden rice is not yet ready for commercial sowing, despite years of experimental planting conducted by the International Rice Research Institute (IRRI) in the Philippines. Moreover, experimental planting done by the IRRI has shown that golden rice has a lower yield than conventional rice varieties. The IRRI published on its website a statement on the results of field trials on the crop: Preliminary results were mixed. While the target level of beta-carotene in the grain was attained, average yield was, unfortunately, lower than that from comparable local varieties already preferred by farmers [22].

Furthermore, in a study published in 2017, Indian researchers found that golden rice genes had unwanted side effects. When they introduced the golden rice genes into their high yielding and agronomically superior variety of indica rice, it turned pale and stunted, the flowering was delayed, and the roots grew abnormally. The yields were so reduced that it was not suitable for cultivation [23].

The study's authors identified several reasons for the unexpected effects – the new gene constructs interfered with the plant's gene for producing growth hormones, and the additional gene constructs were not, as intended, active solely in the kernels, but also in the leaves, resulted in a substantial reduction in the content of chlorophyll that is essential for vital functions in the plants. These unintended effects were not detected in previous investigations, and it was assumed that the genetically engineered plants used in these trials would show genetic stability. But these

detrimental genomic effects remained undetected until the transgenic plants were crossed with the variety called Swarna, which is grown widely in India [24]. Why this is happening is best described by Dr Michael Antoniou: “I have always asserted that the GM transformation process as used in the development of GMO crops selects for the insertion of the GM gene into active regions of the genome (areas where plant host genes are switched on and functioning). This bias in the GM gene insertion into active regions, therefore, maximizes the possibility of disrupting the function of one or more host genes, with potentially adverse effects such as poor crop performance or even toxicity. This latest finding of the GM gene insertion into a vital host gene in the golden rice is a graphic illustration of this principle. If the developers of golden rice had conducted a proper molecular characterization of this GM event at the time it was generated, they would have identified the host gene disruption that led to the stunted and deformed growth of the rice plants. Then they could potentially have avoided this negative outcome at such a late stage in the development and release of golden rice. Now it’s back to square one, with years of research work and millions of dollars wasted” [25].

2. Issues with cross-fertilization and unintended changes in the genome of plants

Another big problem is the possible negative impact on the environment through cross-fertilization with wild rice. Studies confirm that hybrids are resulting from cross-fertilization exhibit unexpected biological characteristics, such as better features in the vegetative and reproductive stages, longer stems, more shoots, and sprouts per plant [26]. These effects can cause the uncontrolled spread of these hybrid plants in the environment. Researchers remain surprised by the improved ability of plants, as specific alterations cannot explain these changes to the genome of the plant achieved through genetic engineering. Scientists have a minimal ability to predict the proliferation potential and biological characteristics of transgenic rice and its hybrids. Another problem is that, when switching to local rice varieties, significant fluctuations in the vitamin A content of rice can occur. The genetically modified construction is not always transferred reliably from the original genetically modified rice plant to the next generation [27]. Experts point out that the cross-breeding of plants results in a higher number of genes altering activity, whereas it does not occur in transgenesis (see, for example, [28], [29]).

Changes in the activity of genes are widespread in the processes of plant breeding. Plants also respond naturally to environmental conditions by adjusting their gene activity. Reproduction and growth can also cause activity that leads to many altered genes at the same time. However, the number of changed genes is not of great importance since certain segments of DNA are entirely under the control of the complex mechanisms of natural gene regulation, and flexible system that responds to changes in conditions in a way that synchronizes the activity of genes. In the process of genetic modification of plants, natural mechanisms of gene regulation are not used. Moreover, they are deliberately circumvented. In a genetically modified plant, the action of inserted genes regulated promoters that are not susceptible to general gene regulation in plants and that regulate the expression of inserted genes. The result is that genetically modified plants cannot control this new metabolic pathway. Some plants respond to the introduction of foreign genes by excluding or deactivating newly inserted genes; this phenomenon is called gene silencing. Plants use this natural defense mechanism, which serves them as a defense against viral DNA contamination [30].

Therefore, promoters that forcibly activate genetically modified inserted genes are used to prevent inactivation of the inserted genetically modified genetic construct and to ensure its natural expression. We can conclude that scientists are trying to use genetic engineering to reprogram plants. Conversely, conventional plant breeding uses the natural genetic potential in plants and their gene regulation system. This distinction is fundamental both to clarify health risks and to evaluate the consequences of entering the transgene in ecosystems and gene pool of wild and cultivated plants. Any changes in the expression of native genes in a plant caused by the insertion of additionally inserted genes should always be carefully examined, as this may be an indicator of disturbance in the normal gene regulation system.

Since the insertion of a gene into a genetically modified plant, despite claims by proponents, is not a precise process, it can be expected that the genetically modified genes will be implemented at a disadvantageous position in the plant genome and lead to a pleiotropic effect (when the gene affects

several traits simultaneously). Genetic intervention as a result of the insertion of a genetically modified gene into a plant can result in a range of biological effects that are relevant for risk assessment. Possible reactions include general weakening of the plant such as increased susceptibility to disease, lower yields, decreased plant tolerance to stress such as climatic conditions, but also improved plant ability through, for example, increased the production of pollen and seeds or production of unwanted, anti-nutritional, immunogenic or toxic components. For example, in golden rice, there is an unintended change in the composition of the carotenoids in the rice stem [31].

Newly inserted genes are active throughout the plant, not only in the grain, for example, and so they interact with components in other parts of the plant. For now, it is unclear what effect this has on the golden rice plant as a whole. Critics fear that certain environmental conditions may cause adverse reactions in genetically modified plants, or that such unplanned and possibly harmful reactions will occur after sowing several successive generations of plants. It is interesting to note that systematic studies on the interaction of genetically modified plants and their environment are not currently required as part of the process for authorizing the sowing of genetically modified plants in the EU. However, it should be noted that there is a growing body of scientific research dealing with the occurrence of undesirable traits in genetically modified plants such as petunia [32], cotton and maize [33], potatoes [34], wheat [35] and soybeans [36]. The research mentioned above clearly demonstrates the necessity of such research to evaluate the environmental impact of genetically modified plants. The study of genetically modified wheat showed that, unlike plants from greenhouses that do not show unexpected reactions, wheat plants that are grown on the experimental field had significantly lower yields and have shown higher rates of infection with the highly toxic ergot fungi. This research clearly shows us how relevant these questions are for risk assessment [37].

Therefore, Zeller in their research require studies of the environmental behavior of genetically modified plants. Furthermore, [38] they recommend the introduction of stress tests in their research. In the process of deciding on the release of genetically modified golden rice in the environment, we should be aware of the following facts. In regions where future sowing of golden rice is planned, there is a weed rice (a type of wild rice classified and treated as weed) with which golden rice can easily cross pollen and thus insert modified genes into weed rice. Wild rice species are widespread in many agricultural regions [39] [40]. Genetic crossing between cultivated rice fields and wild varieties that grow in an environment often occurs [40]. In such circumstances, it is difficult to prevent the uncontrolled spread into the environment of genotypes whose natural regulation of genes has been modified by the technical application. There is a real possibility that genetically modified genes can spread and accumulate in weed rice [40]. Research done in China shows that hybrids resulting from cross-breeding between genetically modified rice and its wild relatives may show unexpected biological characteristics. For example, the concentration of Bt toxin in genetically modified rice, which is deadly to insects and therefore serves as an insecticide in agriculture, has been significantly increased in some plants that have resulted from the cross-fertilization of plants genetically modified rice and the wild rice varieties [41].

Furthermore, these hybrid plants had improved biological capabilities compared to non-transgenic parent plants [42], and this may lead to an increased spread of these plants in the future. The improved ability of hybrid plants was unexpected, and scientists cannot explain the specific changes that have occurred as a result of the genetic modification of the plant. Scientists are limited in their ability to predict the potential for uncontrolled spread and biological features of genetically modified rice and its cross-breeds. In any case, it seems unlikely that foreign genetically modified genes, once spread among the wild population, can be restricted or returned to the laboratory (see [43]). Recent research shows that future climate change will cause genetically modified genes to move even faster and easier into the rice weed population [44]. Simple cross-breeding features of genetically modified rice can remain inactive for a long time, and that is why it poses a threat to the ecosystem and can cause serious difficulties in the cultivation of rice in general. For example, that future generations will cross-breed and contaminate the environment with genetically

modified genes. Genetic exchange is not a one-way street, and it goes both ways. The exchange of genes between cultivated conventional rice fields and the surrounding varieties of wild rice is a common phenomenon. The same rule applies to genetically modified rice. Pollen of wild rice varieties can potentially take genetically modified genes in case of their mutual cross-breeding, back in the field - even in fields where conventional rice is grown.

Thus, the cultivation of golden rice potentially threatens to cause unpredictable and extremely problematic scenarios by leaps.

1. Potentially there is a cross-breeding of genetically modified varieties of rice crops and their wild relatives, which can exhibit remarkable biological properties that can be rapidly expanded into the environment, with unpredictable environmental consequences.
2. Once genetically modified foreign genes are mixed with wild rice populations, it is no longer possible to control, limit, or reverse their spread.
3. Besides, one should be aware that as the genetically modified foreign genes spread in the population of wild rice, contamination of conventional rice crops is inevitable, and what it means for the security of supply of food should not be emphasized.

We can conclude that in the case of future commercial planting of golden rice it is necessary to adhere to the guidelines outlined in the work of Bauer-Panskusa and associates point out the following: The possibility of eliminating genetically modified plants should be a prerequisite for their use. The medium and long-term effects of their release on evolutionary processes, biodiversity, and human health cannot be scientifically predicted with the appropriate degree of certainty. The release of genetically modified crops into the environment can only be accepted if the length and location of the release can be controlled (see [45]). We conclude that if these guidelines were followed in the assessment of the authorization to plant genetically modified golden rice, sowing would be prohibited.

CONCLUSION

The case of golden rice has caused controversy and public attention for 19 years. The tremendous promise of saving millions of children from blindness and death due to planting and consumption of golden rice has not been fulfilled. Golden rice proponents blame opponents of biotechnology, led by Greenpeace, and strict regulatory rules for the commercial delay in golden rice commercial sowing. As seen in the paper, the truth is much simpler. Due to its complexity and problems encountered, from reduced yields, through the volatility of the amount of beta-carotene in the rice itself, to the possibility of genetic contamination through cross-breeding with rice weeds, golden rice is still not commercially sown, and it is very doubtful whether it will ever be ready for commercial sowing. The failure of successful cultivation of golden rice, once again, confirms how difficult it is for a trait that has been successfully genetically modified and implemented into a plant in the laboratory to convey into the environment and the real world without a multitude of potentially harmful and unwanted side effects. The golden rice saga confirms the views of critics on the myriad of unknowns surrounding this technology, and it is only reasonable in the development and eventual sowing of golden rice to adhere strictly to the precautionary principle, since, as research shows, irreversible environmental damage can and potentially will occur.

REFERENCES

1. Nash JM. This rice could save a million kids a year. *Time Magazine*. 2000 Jul 31;31.
2. James C. Global status of commercialized biotech/GM crops, 2011. Ithaca, NY: ISAAA; 2011.
3. Tang G, Qin J, Dolnikowski GG, Russell RM, Grusak MA. Golden Rice is an effective source of vitamin A. *Am J Clin Nutrition* 2009;89(6):1776-83.
4. Lee H, Krimsky S. The arrested development of Golden Rice: the scientific and social challenges of a transgenic biofortified crop. *Int J Soc Sci Stud* 2016;4:51.
5. Yu X, Li W. Informed consent and ethical review in Chinese human experimentation: reflections on the "Golden Rice Event". *Biotechnol Law Report* 2014;33(4):155-60.

6. Qiu J. China sacks officials over Golden Rice controversy. *Nature* 2012,Dec 10.
7. Achenbach J. 107 Nobel laureates sign letter blasting Greenpeace over GMOs. *Washington Post*. 2016 Jun 30;30.
8. ML Guerinot, *The Green Revolution Strikes Gold* (ed. D Castle; M Ruse). Genetically Modified Foods, Prometheus Books, New York. 2002; pp41-4.
9. D Castle, Ruse M. *Genetically Modified Foods*. Prometheus Books, New York. 2002; pp52.
10. Chassy BM. Food safety risks and consumer health. *New Biotechnology* 2010;27(5):534-44.
11. Potrykus I. Regulation must be revolutionized. *Nature* 2010;466(7306):561-2.
12. Lomborg B. The deadly opposition to genetically modified food. *Slate*.
13. Enserink M. Tough lessons from golden rice.
14. Nestle M, Greger JL. Genetically engineered" golden" rice unlikely to overcome vitamin A deficiency/Response. *J Acad Nutr Diet* 2001;101(3):289-96.
15. Scott D. The technological fix criticisms and the agricultural biotechnology debate. *J Agricult Environ Ethics* 2011;24(3):207-26.
16. Rosset P. Genetically modified crops for a hungry world: How useful are they really. *Tailoring Biotechnologies* 2006;2(1):79-94.
17. Stevens GA, Bennett JE, Hennocq Q, Lu Y, De-Regil LM, Rogers L, Danaei G, Li G, White RA, Flaxman SR, Oehrle SP. Trends and mortality effects of vitamin A deficiency in children in 138 low-income and middle-income countries between 1991 and 2013: a pooled analysis of population-based surveys. *Lancet Glob Health* 2015;3(9):e528-36.
18. Paine JA, Shipton CA, Chaggar S, Howells RM, Kennedy MJ, Vernon G, Wright SY, Hinchliffe E, Adams JL, Silverstone AL, Drake R. Improving the nutritional value of Golden Rice through increased pro-vitamin A content. *Nat Biotechnol* 2005;23(4):482.
19. Swamy BM, Samia M, Boncodin R, Marundan S, Rebong DB, Ordonio RL, Miranda RT, Rebong AT, Alibuyog AY, Adeva CC, Reinke R. Compositional analysis of genetically engineered GR2E "Golden Rice" in comparison to that of conventional rice. *J Agricult Food Chem* 2019;67(28):7986.
20. Bollinedi H, Dhakane-Lad J, Krishnan SG, Bhowmick PK, Prabhu KV, Singh NK, Singh AK. Kinetics of β -carotene degradation under different storage conditions in transgenic Golden Rice® lines. *Food Chemistry* 2019;278:773-9.
21. Office of Dietary Supplements. Vitamin A: Factsheet for Health professionals [Internet]. National Institutes of Health Office of Dietary Supplements. 2019.
22. Wilson A, Latham J. GMO golden rice offers no nutritional benefits says FDA. *Independent Science News* [Internet]. 2018 June 3. Available from: <https://www.independentsciencenews.org/news/gmo-golden-rice-offers-no-nutritional-benefits-says-fda/>
23. Vukovar. Agriculture in Nature and Environment Protection [Internet]. 11th Scientific / professional conference on Agriculture in Nature and Environment Protection; May 28-30, 2018; Republic of Croatia. Osijek: Ivan Simic [2018 May 28-30]. Available from: <http://www.hdpot.hr/images/files/Vukovar%20zbornici/Vukovar%20-%20Zbornik%202018.pdf>
24. Bollinedi H, Prabhu KV, Singh NK, Mishra S, Khurana JP, Singh AK. Molecular and functional characterization of GR2-R1 event based backcross derived lines of golden rice in the genetic background of a mega rice variety Swarna. *PloS One* 2017;12(1):e0169600.
25. Then C. Data on 'Golden Rice' not sufficient to show health safety and indicate low benefits [Internet]. Testbiotech. IIIAB. 2018 Feb 5. Available from: <https://www.testbiotech.org/en/news/data-golden-rice-not-sufficient-show-health-safety-and-indicate-low-benefits>
26. Testbiotech. GMO golden rice shows stunted and abnormal growth with reduced grain yield. *GMWatch*. 2017 Feb 16. Available from: <https://gmwatch.org/en/news/latest-news/17470-gmo-golden-rice-shows-stunted-and-abnormal-growth-with-reduced-grain-yield>
27. Lu BR, Yang C. Gene flow from genetically modified rice to its wild relatives: Assessing potential ecological consequences. *Biotechnol Adv* 2009;27(6):1083-91.
28. Chikkappa GK, Tyagi NK, Venkatesh K, Ashish M, Prabhu KV, Mohapatra T, Singh AK. Analysis of transgene (s)(psy+ crtI) inheritance and its stability over generations in the genetic background of indica rice cultivar Swarna. *J Plant Biochem Biotechnol* 2011;20(1):29-38.
29. Batista R, Saibo N, Lourenço T, Oliveira MM. Microarray analyses reveal that plant mutagenesis may induce more transcriptomic changes than transgene insertion. *Proc Natl Acad Sci* 2008;105(9):3640-5.
30. Glenn KC. Nutritional and safety assessments of foods and feeds nutritionally improved through biotechnology: Lysine maize as a case study. *Journal of AOAC International* 2007;90(5):1470-9.
31. Finnegan J, McElroy D. Transgene inactivation: plants fight back!. *Biotechnology*. 1994;12(9):883.

32. Schaub P, Al-Babili S, Drake R, Beyer P. Why is golden rice golden (yellow) instead of red?. *Plant Physiol* 2005;138(1):441-50.
33. Meyer P, Linn F, Heidmann I, Meyer H, Niedenhof I, Saedler H. Endogenous and environmental factors influence 35S promoter methylation of a maize A1 gene construct in transgenic petunia and its colour phenotype. *Mol Gen Genetics* 1992;231(3):345-52.
34. Then C, Lorch A. A simple question in a complex environment: How much Bt toxin do genetically engineered MON810 maize plants actually produce. 2008) Implications of GM-Crop Cultivation at Large Spatial Scales., *Theorie in der Ökologie*. 2008;14.
35. Matthews D, Jones H, Gans P, Coates S, Smith LM. Toxic secondary metabolite production in genetically modified potatoes in response to stress. *J Agricult Food Chem* 2005;53(20):7766-76.
36. Zeller SL, Kalinina O, Brunner S, Keller B, Schmid B. Transgene× environment interactions in genetically modified wheat. *PLoS One* 2010;5(7):e11405.
37. Gertz JM, Vencill WR, Hill NS. Tolerance of transgenic soybean (*Glycine max*) to heat stress. In *BRIGHTON CROP PROTECTION CONFERENCE WEEDS 1999* (Vol. 3, pp. 835-840).
38. Zeller SL, Kalinina O, Brunner S, Keller B, Schmid B. Transgene× environment interactions in genetically modified wheat. *PLoS One* 2010;5(7):e11405.
39. Then C, Potthof C. Risk Reloaded: Bericht zum Umgang mit den Risiken gentechnisch veränderter Pflanzen in der EU [Internet]. 2009 October. München; Testbiotech. Available from: https://www.testbiotech.org/sites/default/files/risk-reloaded_deutsch_4.pdf
40. Delouche J et al. Weedy rices- origin, biology, ecology, and control [Internet]. Food and Agricultural Organization of United Nations. 2007. Rome; FAO Plant Production and Protection Paper.
41. Chen LJ, Lee DS, Song ZP, Suh HS, LU BR. Gene flow from cultivated rice (*Oryza sativa*) to its weedy and wild relatives. *Ann Botany* 2004;93(1):67-73.
42. Xia H, Lu BR, Su J, Chen R, Rong J, Song Z, Wang F. Normal expression of insect-resistant transgene in progeny of common wild rice crossed with genetically modified rice: its implication in ecological biosafety assessment. *Theoret Appl Genetics* 2009;119(4):635-44.
43. Lu BR, Yang C. Gene flow from genetically modified rice to its wild relatives: Assessing potential ecological consequences. *Biotechnol Adv* 2009;27(6):1083-91.
44. Bauer-Panskus A, Breckling B, Hamberger S, Then C. Cultivation-independent establishment of genetically engineered plants in natural populations: current evidence and implications for EU regulation. *Environmental Sciences Europe* 2013;25(1):34-8.
45. Ziska LH, Bunce JA, Shimono H, Gealy DR, Baker JT, Newton PC, Reynolds MP, Jagadish KS, Zhu C, Howden M, Wilson LT. Food security and climate change: on the potential to adapt global crop production by active selection to rising atmospheric carbon dioxide. *Proc Royal Soc B: Biol Sci* 2012;279(1745):4097-105.

Acknowledgements – Nil
 Source of Funding – Nil
 Conflict of Interest – Nil

Ethical concerns in Animal Cloning: Possible Risks and Assessment

Neha Sinha¹, Sharvil Patil², Udaya Kesigan³, T. Sai Chaitanya⁴, Simran Panigrahy⁵, G.D. Tandon⁶

^{1,2,3,4,5}M.Tech. Integrated Biotechnology 4th year (VII Sem), Dr. D. Y. Patil Biotechnology and Bioinformatics Institute Pune.

⁶Faculty, Department of Bioechnology, Dr. D. Y. Patil Biotechnology and Bioinformatics Institute Pune.

Corresponding Author: G.D. Tandon

E-mail: g.tandon@dpu.edu.in

ABSTRACT

The disciplines of biotechnology include various techniques that make use of biological systems or processes for the benefit of the human being. Living systems and organisms involved in biotechnology are used to develop, make, and modify products like antibiotics, vaccines, cloned animals, and the confectionery industry for their specific use. The science of ethics asks us to explain our actions and accounts for our objectives. Bioethics includes evaluation and use of ideas like right, wrong, evil and responsibility. It includes ethical issues arising from advancements in biology and medicine. It is related to many significant issues with respect to human, animal, food, and health. As we move from research to technology ethical questions emerge with respect to shielding human subjects and society from instability and misuse by researchers. The present study emphasizes the correlation of bioethical issues arising from animal cloning. The animal can be used for various purposes like reproductive and non-reproductive or therapeutics. Bioethics is used to minimize the harm done to living beings. The presumption is that all animals will avoid pain, distress, or death if given the choice, therefore it is ethical for humans to reduce exposing animals to these events. Circulation of information about the existing ethical considerations and other possibilities in animal experiments has two important roles; 1) it increases the awareness of the researchers for possible methods of using animals in the experiments, and 2) to ensure that the researchers are aware of the established alternatives.

Keywords: Biotechnology, bioethics, risk, bioethical issue, misuse, animal cloning.

INTRODUCTION

Biotechnology is a field of science that uses biological means to create products that benefit mankind. Techniques such as genetic engineering, cloning, r-DNA and other technologies which lead to the production of genetically modified products with enhanced characteristics. Though the applications of biotechnology are beneficial to mankind still, there is a possibility of some potential risks that might have some disastrous effect, therefore it becomes mandatory to follow the principles of "Bioethics" to avoid such disastrous events.

The word "Bioethics" is derived by merging two Greek words bios: life and ethike: ethics which deals with bioethical issues. It is a branch of ethical science that studies the [1] controversial ethical

aspects such as philosophical, cultural, social, and legal issues arising in the fields of medical, biotechnological and other life sciences. It is a multi-disciplinary field that deals with ethical implications arise due to some practices in biological fields and helps in resolving them [2]. The concept of bioethics is commonly understood as a collective term for three broad fields viz. medical ethics, animal ethics, and environmental ethics. It is not a matter of local affairs that can be resolved by a local society, instead, they are worldwide issues having universal effects [2]. In general bioethics deals with subjects like 1) Human diagnostics 2) Agriculture 3) Synthetic biology 4) Patenting 5) Biotech and pharmaceutical companies 6) Gene Therapy 7) Stem cell research 8) Clinical Trials 9) Environment 10) Animal cloning etc. The important ones closely related to the present article are discussed as follows:

- **Gene Therapy:** It is the technique used to rectify some of the defective genes by manipulating the expression of certain genes for treating a disease. However various side effects like leukemia and even death have been observed.
- **Stem cell therapy:** Stem cells have an ability to differentiate into many different types of cells. Stem cell therapy is a new field of medical science that uses stem cells for the regeneration of dead cells or for generating organs for organ transplantation. [3]
- **Clinical Trials:** These are clinical studies taken upon animals or human beings for analysing medical, surgical, or behavioural interventions. It is the way to find out whether a new treatment such as new drugs, a new diet or a new medical device is going to be safe and effective or have some harmful side effects.
- **Environmental ethics:** It is the branch of applied ethics that deals with the study of moral values of human being towards the environment. [4]
- **Animal cloning:** Animal cloning is the process of creating a genetically identical replica of a cell or an organism [5]. Further details, particularly about animal cloning, are discussed later in this article.

History of bioethics

During the seventies, people considered that the term “Bioethics” was coined by an American Biochemist Van Rensselaer Potter. In his article, he linked Mankind, nature, culture, science, and values [6]. He had a prominent role in the formation of today’s Bioethics which led to the development of new discipline to address the ethical issues raised in the field of medical and life sciences. But according to the literature, it appears that the word bioethics has been referred to earlier in 1927 by German protestant, Fritz Jahr in his article “Bio-Ethik. Eine Umschau über dies ethischen Beziehungen des Menschen Zu Tier und Pflanze, which was later mentioned in a conference by Rolf Löther in 1997” [7]. After the discovery of his work in 1997, Fritz Jahr (1895–1953) has gradually acknowledged as the author of the term and concept of Bioethics [8]. The name of US political activist Sargent Shriver is also mentioned in the literature as a pioneer who used the term ‘bioethics’ in 1970 when they opened the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics at Georgetown University.

Animal cloning

Cloning is a process used to create a genetically identical replica of another cell, tissue, organ or an organism [9]. The replica is known as a clone that has the same genetic makeup as the original. Typically, there are three different types of cloning:

- **Gene cloning:** This process creates a duplicate set of genes or segments of DNA that can identify certain genetic abnormalities.
- **Reproductive cloning:** This process creates copies of the entire animal.
- **Therapeutic cloning:** This process creates embryonic stem cells which can be utilized for medical use.

Scientists have successfully cloned many animal species (Table:1) such as primates, dogs, and a host of endangered animal species.

Table 1: List of cloned animals

Sr. No.	Cloned animals	Year	First Citation
1	Sea Urchins	1885	Hans Adolf Eduard Driesch et al. (1885)
2	Salamanders	1902	Hans Spemann et al. (1902)
3	Fish Cloned	1952	Tong Dizhou et al. (1963)
4	Cloning of Frogs	1958	Robert Briggs and Thomas King et al. (1958)
5	Rabbits	1975	Chesne et al. (2002)
6	Cows	1987	Forsberg et al. (2002)
7	Dolly the sheep's born	1996	Wilmur et al. (1997)
8	Monkeys; Transgenic technology introduced	1997	Li Meng et al. (1997)
9	Mice	1998	Wakayama et al. (1998)
10	Endangered Gaur and interspecies surrogacy & therapeutic cloning introduced	2001	Lanza et al (2000)
11	Cat	2001	Shin et al. (2002)
12	Human Genome project done – banteng,	2003	Sansinena et al. (2005)
13	Deer	2003	Texas A&M announcement (2003)
14	Horse	2003	Galli et al. (2003a)
15	Mule	2003	Woods et al. (2003)
16	UN adopts a ban on all human cloning: dog, Japanese team plans to bring back mammoths	2005	Lee et al. (2005)
17	Wolves	2007	Kim et al. (2007)
18	Goat	1999	Keefer et al. (2002)
19	Rat	2002	Zhou et al. (2003)
20	Wildcat	2003	Gomez et al. (2003)
21	Ferret	2006	Li Z et al. (2006b)
22	Swamp Buffalo	2006	Suteevun et al. (2006)
23	Pig	2000	Polejaeva et al. (2000)
24	Mouflon Sheep	2000	Loi et al. (2001)

Evolution of animal cloning

There are a number of reports describing animal cloning in the past. In 1901, the nucleus of salamander from its embryonic cell was transferred to an enucleated cell. During the mid 19th century, scientists were able to clone embryos in mammals and in 1962, the mature frog was developed by transferring the nucleus of intestinal cells of tadpoles into enucleated eggs [10]. Later in 1984, Sheep cloning from embryonic cells was attempted. In 1994, bovine cloning was tried from embryonic cells taken from another cow [9].

In 1995, the first successful animal cloning was made by Ian Wilmut et.al. at the Roslin Institute in Scotland; cloning two lambs viz. Megan and Morag. The lambs were cloned from cells taken from an early embryo. The same scientists cloned Dolly sheep one year later using somatic cells

[11]. The Dolly sheep was created using mature cells of mammary glands from a mature sheep (Figure 1) [9]. In general, the success rate of animal cloning is quite low and ranges from 0.1 percent to 3 percent, which signifies that for every 1000 attempts, only 1 to 30 clones are made. A cloning project was launched by the Korean scientists to produce pigs with genetically altered hearts [12]. Various agricultural researchers produced different types of cloned animals with altered genes making their milk or meat healthier for consumers, further disease-resistant clones were also created to narrow down the environmental burden e.g. cows that are resistant to brucellosis were cloned by scientists at A&M University Texas [13]. Now scientists are focussed on cloning goats so as to produce milk with less fat; *featherless* chicken to reduce the costs of poultry farming and pigs whose manure has very low phosphorus which helps to limit the environmental pollution [14].

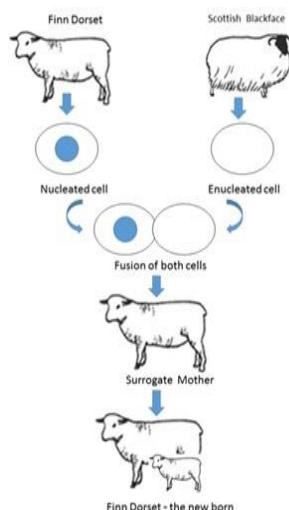


Fig.1. First successful Cloning of animals (Taken from: Izaarbe (2010) 'Cloning Techniques and Gene Therapy', *Biology & Geology* 4 ESO, 5 April.
<https://bio4esobal2009.wordpress.com/2010/04/05/cloning-techniques-and-gene-therapy/>)

Figure 1: First successful cloning of animals

Many endangered or even extinct species may be restored soon by animal cloning. In 2001 Indian bison (a type of wild ox) which was on the verge of extinction was cloned but unfortunately died in the early stage of growth due to dysentery which is not related to the cloning process [15]. There are many on-going projects to restore various extinct species like Thylacine, Asian cheetah, and Woolly mammoth by cloning techniques [16]. One of the well-known and difficult cloning projects is the Missyplicity Project, in which they cloned a dog who had died, but three cloned puppies were born and delivered to the owner [17]. Later on, a project known as CopyCat was launched with an objective to clone the cats.

There have been a few public discussions on a number of ethical issues related to animal cloning projects. A number of surveys have been made in the past describing ethical issues in animal cloning. One such survey done by Gallup in 2005, (Figure.2.) describes the views of Americans suggesting animal cloning which seems to be ethically wrong [18]. It is not clear from this survey whether it was a public decision or a public reaction? [11].

Ethics of cloning

Animal cloning may give rise to two different types of moral problems 1. It may create some negative impacts on animals, human beings and the environment; 2. It may disobey various important moral principles [19, 20]. The negative impacts that occur to animals can be understood both narrowly and broadly. Narrowly understood negative impact includes pain & suffering which are the most serious consequences experienced by animals during the cloning process. While the

broadly understood negative impact on animals includes the adverse effect of cloning on other animals or threatened species.

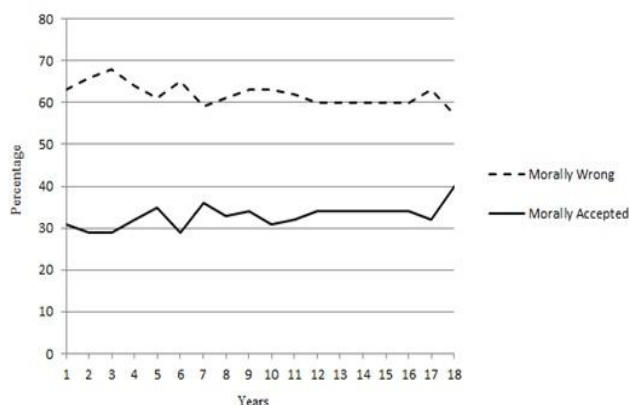


Fig.2: Graph showing the percentage of Americans for and against animal cloning (data taken from [Saad 2004](#)).

Figure 2: Percentage of Americans for and against cloning

Statistical data on the success rate of animal cloning procedures and the health of animals shows a gloomy view. A large number of literature citations have shown high rates of spontaneous abortion, premature death, stillbirth, genetic disorders, chronic illness in cloned animals. Due to the above mentioned problems the efficiency of animal cloning has drastically reduced to about 1-2% which means only 2 out of 100 embryos get successfully implanted in surrogate animals and become offspring [21, 22]. Despite of their efficiency rates are at their best, the overwhelming majority of successful attempts failed to be fruitful.

Efficiency formula may be stated as:

$$\text{Percent efficiency in animal cloning} = \frac{\text{Number of live offspring produced}}{\text{Total number of transferred embryos}} * 100$$

Risk to clone animals

From the literature, the term "risk" is commonly used and has many different meanings. Risk is defined as a "chance or possibility of danger, loss, injury, etc." In relation to animal cloning, risk can be defined as a possibility to cause potential effects to cloned animals, surrogate dams and the environment. Risk assessment is the process of evaluating the possible risks arise due to animal cloning process.

The animals involved in animal cloning experiments are subjected to high risks adversely affecting them which includes abnormal placentation, pregnancy toxemia, and hydroallantois. In one study it was found that 5 out of 10 cloned pigs died between 3-130 days of age from sickness like chronic diarrhoea, congestive heart failure and decreased growth rate which results in a 50% mortality rate [23]. In another study also the case of early death of cloned mice has been reported [24]. Other findings in studies on calves show that there were 106 live births out of 2170 implanted embryos in which 24 died shortly after birth and 11 out of them showed severe physiological abnormalities like abdominal disorder, musculoskeletal abnormalities, Genito-urinal abnormalities, pulmonary failure, etc. A statistical analysis from multiple scientific studies with respect to the health status

of clones revealed that 77% of cloned animals show no developmental abnormalities throughout the conduct. These adverse effects on animals due to cloning experiments led several international animal organizations to stand against it [25].

Philosophical Views

Several debates have held over a period of time to discuss the validity of animal cloning. It was concluded to ban the use of products from cloned animals and to prevent the use of animal cloning. For example, the U.S. Humane society which is an animal protection organization has requested to ban on products coming from cloned animals and their offspring. The vice president of this organization, Michael Appleby stated that the animal welfare problems that already exist will increase with the new biotechnological practices e.g., disease vulnerability. He argued: "Already animals are suffering from maladies at a rate unheard of before we applied biotechnology to the barnyard. It would be disastrously premature to put this technology into commercial practice" [26].

Religious views

Many religions have various guidelines or principles on doing things in the right way, on how should we live. Various philosophers proposed many ethical traditions or principles which can be classified into two categories 1) secular 2) spiritual [27].

Some ethical or moral theories are included in the secular division or western division, whereas religion comes under the spiritual division [27]. According to the Islamic religion research, one has to ultimately find the truth and to observe the signs of Allah's glory in order to understand natural phenomena and the hidden story behind the universe [28].

In the early Christian era, St. Augustine (AD 354 - 430) a theologian and Neoplatonic philosopher was highly influential. He mentioned that the percept "Thou shalt not kill" is not applicable to animals, because as they do not object and are unlike humans. According to him, God created an animal for the betterment of humans so people should also protect animals for their own uses.

Use of cloned animals for food and health

The impact of food production from cloned livestock arose many questions. One part of the question is ethics and the other part is science. The next question arises about the safety of such food to eat. However, in late October 2003, the US FDA stated that no evidence could be found against the safety of the food and milk derived from cloned animals [29]. But in another statement, they claimed that due to lack of sufficient information it was not possible to justify that cloned food was safe [30]. Finally, in 2008 after gathering the safety data from USDA the US FDA approved the use of cloned animals for their food and milk products [31].

The pain, sufferings, and difficulty that animals feel due to cloning procedures can be justified by their noble uses like curing humans and animal diseases or protecting threatened species. It should be permissible for this reasons because it is helpful in solving the pain of human being and other animals but it should not be permissible for the reasons like making animals more attractive for art purposes, for example, the deer's are cloned to get large antler and to make them more attractive to hunters or production of chimera to keep them as an art object [11].

Other advantages and applications of animal cloning

The advantages and applications of animal cloning are far beyond that of the ability of human thinking. Though some important applications of animal cloning can be (i) Recreation and replication of animals that are going to be extinct (ii) the possibility of selective breeding by cloning animals of desired characteristics. (iii) Generation of transgenic farm animals as animal models to study some human diseases [32]. (iv) Solving the issues of infertility by using some alternative approaches like IVF (In vitro fertilization) (v) improving the products from live stocks by cloning animals of better quality (vi) possibility in production of human therapeutics as well as xenograft tissues and organs with the help of somatic cloning, coupled with genetic modifications [33].

Disadvantages of Cloning

As the cloning is a new and uncommon procedure, its end results are still not clear in public mind due to which there have been internal and external conflicts. Internal conflicts include i) If the cloned animals are susceptible to face genetic problems and difficulty for survival in the long term, (ii) The more the cloned animals the more their extinction probability due to the changes in their genetic makeup which may increase the probability of death due to infections, as the clones may not have required immunity. (iii) the repeated cloning might result in the creation of monsters (iv) the creatures could be susceptible for the diseases such as cancer, (v) Premature aging: the clones are likely to grow older due to the premature aging e.g., if the donor is 40 years old then the new-born will also be 40 years old like it happened in the case of Dolly sheep [9].

CONCLUSIONS

Bioethicists are dealing with the various ethical issues with regard to law, medicine, biotechnology, life sciences, and philosophy. The controversy about the origin of the term Bioethics still remains unsolved between Fritz Jahr, Van Rensselaer Potter or Sargent Shriver [34, 35] but the name of Potter is prevailing. Though some of the applications in animal cloning are beneficial, however, most of them have adverse effects. The success rates in animal cloning are relatively low compared to expected outcomes and the efficiency of animal cloning process is quite less around 1-2%. Also, the animals involved in cloning experiments may pose some potential risks to their life and to other animals. Bioethics is concerned with moral aspects, for the use of the animals in cloning experiments. It is a new and interdisciplinary field that helps in understanding and solving several ethical issues arising in the fields of food, medicinal, and life sciences. It may be considered as a better and useful way to protect threatened species and to recreate endangered species.

Though some organizations claim that the products derived from cloned livestock are harmful without having any supporting data in favour of their claim. In fact, in 2008 the US FDA has already approved the use of products from such live stocks like milk, meat...etc. for human consumption. Ethically justifiable conclusions depend on two kinds of judgments: factual (based on scientific evidence and theories), and ethical (based on the best available moral philosophy theories) one can say that the problems in animal cloning prevail over their benefits, requiring bioethical controls.

REFERENCES

1. Sodeke SO. Tuskegee University experience challenges conventional wisdom: is integrative bioethics practice the new ethics for the public's health?. *J Health Care Poor* 2012;23(4):15.
2. Twine R. *Animals as biotechnology: ethics, sustainability and critical animal studies*. Routledge; 2010.
3. Railton, D. 'What are stem cells and why are they important?'. *Medical News Today*. 2019 Feb 8. Available from <https://www.medicalnewstoday.com/articles/200904.php>
4. Jamieson D, editor. *A companion to environmental philosophy*. John Wiley & Sons; 2008.
5. LaFort R, NRC KL, Tiraspolsky M. *Implementing GM Technology in Order to Safeguard Endangered Species in Our Continuously Changing Environment*. From umass.edu
6. Lopes M. LEGALIZAÇÃO DA MACONHA: DEBATE POLÍTICO, SOCIAL E JURÍDICO SOBRE SUA PERTINÊNCIA.
7. Muzur A, Rinčić I. Fritz Jahr (1895-1953): a life story of the "inventor" of bioethics and a tentative reconstruction of the chronology of the discovery of his work. *Jahr* 2011;2(4):385-94.
8. Rinčić I, Muzur A. Fritz Jahr: The invention of bioethics and beyond. *Persp Biol Med* 2011;54(4):550-6.
9. Nabavizadeh SL, Mehrabani D, Vahedi Z, Manafi F. Cloning: A Review on Bioethics, Legal, Jurisprudence and Regenerative Issues in Iran. *World J Plast Surg* 2016;5(3):213-8.
10. Atrak H. Human cloning and Kant's theory. *Iran J Med Ethics Hist Med* 2011;4(6):39-49.
11. Autumn F. Ethical issues in animal cloning. *Persp Biol Med* 2005;48(3):328-44.
12. Newswires DJ. South Korea to mass-produce pig organs for human transplants. June 12.
13. Phillips K. Disease-resistant bull cloned at Texas A&M.
14. Thomas T. Cloned and genetically engineered animals. Humane Society of the United States.

15. Gallagher J. Modifying life: A journey of discovery through the mysterious world of genetics. BBC. 2017 Sept 20. Available from http://www.bbc.co.uk/science/genes/gene_safari/clone_zone/extinct03.shtml.
16. AgBiotechNet. 2001. Cloning hopes for extinct species. 2003. Available from <http://www.agbiotech.net>
17. Science Daily. Texas A&M Clones First Cat. 2002 Feb 15. Available from <https://www.sciencedaily.com/releases/2002/02/020215070841.htm>
18. Saad L. The cultural landscape: What's morally acceptable. Gallup News Service. 2004;22:2-4.
19. Rollin BE. Animal research: a moral science. EMBO Reports 2007;8(6):521-5.
20. Singer P. Animal liberation: a new ethics for the treatment of animals. New York Review, New York. 1975.
21. Coleman A. Somatic cell nuclear transfer in mammals: Progress and application. Cloning 1999;1:185-200.
22. Paterson L. Somatic cell nuclear transfer (cloning) efficiency. 2003. Available from <http://www.roslin.ac.uk/public/webtablesGR.pdf>.
23. Carter DB, Lai L, Park KW, Samuel M, Lattimer JC, Jordan KR, Estes DM, Besch-Williford C, Prather RS. Phenotyping of transgenic cloned piglets. Cloning Stem Cells 2002;4(2):131-45.
24. Ogonuki N, Inoue K, Yamamoto Y, Noguchi Y, Tanemura K, Suzuki O, Nakayama H, Doi K, Ohtomo Y, Satoh M, Nishida A. Early death of mice cloned from somatic cells. Nat Genet 2002;30(3):253-9.
25. Cibelli JB, Campbell KH, Seidel GE, West MD, Lanza RP. The health profile of cloned animals. Nat Biotechnol 2002;20(1):13-9.
26. Humane Society of the United States (HSUS). HSUS asks the FDA to ban sales from cloned farm animals. 2003. Available from <http://www.hsus.org/ace/15431>.
27. Amin L. Modern biotechnology: Ethical issues, ethical principles and guidelines. MALIM 2009;10:3-16.
28. Amin LA, Jahi JM. Ethical Aspects of Genetically Modified Organisms Release into the Environment. Malaysian J Environ Manage 2004;5:99-111.
29. Neergaard L. FDA: Cloned animal meat appears safe. Washington Post. 2003.
30. Associated Press. FDA wants more data on cloned meat safety. Washington Post. 2003 Nov. 4. Available from <http://washingtonpost.com/ac2/wp-dyn/A867-2003Nov4?language=printer>.
31. Lenzer J. US Congress and European Research Council insist on open access to research results.
32. Smith LC, Bordignon V, Babkine M, Fecteau G, Keefer C. Benefits and problems with cloning animals. Can Veterinary J 2000;41(12):919.
33. Wells DN, Oback B, Laible G. Cloning livestock: a return to embryonic cells. Trends Biotechnol 2003;21(10):428-32.
34. Comstock G. Ethics and Genetically Modified Crops: A Brief for the Royal Commission on Genetic Modification of New Zealand.
35. Thomas S. Ethical and social considerations in commercial uses of food and fiber crops. In Proceedings of the First International Symposium on Ecological and Societal Aspects of Transgenic Plantations 2001 Jul 22 (pp. 92-98).

Acknowledgements: Nil

Funding: Nil

Conflict of interest: None

Inclusion of Bioethics in Performance Appraisal for Promoting Ethical Behaviour among Doctors in Hospital

Deepak Singla¹, Bharathi Saxena², Amit Mahajan³

¹Medical Director; Maharaja Agrasen Hospital, Punjabi Bagh, New Delhi.

²Joint Medical Superintendent, Maharaja Agrasen Hospital, Punjabi Bagh, New Delhi.

³PhD Research Scholar, Manav Rachna University, Faridabad

Corresponding Author: Deepak Singla

E-mail: singla1960@gmail.com

ABSTRACT

The growing public concern about the ethical conduct of healthcare professionals, specially the doctors, highlights the need to incorporate clinical ethics in all wakes of medicine be it medical education, CMEs (Continuing Medical Education), working and even performance appraisal. Bioethics, being a new subject, at least for the medical fraternity in India, needs lot of initiatives to reach all the aspects of clinical practice of doctors. One method to ensure that the doctors working in the hospital are following ethical behavior and are aware about the ethical issues in the hospital is to incorporate the 'Ethics Knowledge and Practice by Doctors' in the performance appraisal. The aim of the study is to examine the applicability of 'Ethics Knowledge and Practice by Doctors' in performance appraisal of the doctors so that ethical behavior of doctors could be positively impacted.

This article is based on the secondary research and literature is reviewed from different academic sources which includes articles and previous research being done by other researchers. Existing body of research highlighted that Ongoing Professional Practice Evaluation (OPPE) method is newest model to conduct performance appraisal of doctors. For conducting OPPE six parameters are examined, viz. Patient Care; Medical and clinical knowledge; Practice based learning and improvement; Interpersonal and Communication Skills; Professionalism; and, System based practice. Ongoing Professional Practice Evaluation (OPPE) method is found to be most comprehensive method to conduct performance appraisal of the doctors. 'Ethics Knowledge and Practice by Doctors' could be added in 'Professionalism' parameter of OPPE.

Keywords: Bioethics, performance appraisal, ethical behavior, hospital, appraisal, OPPE.

INTRODUCTION

India medical scenario is seeing a new trend where the healthcare institutions and providers are facing lot of litigation and customers' unrest against the unethical practices. Wynia noted in his article that patients do care about ethics [1]. In India, also, it is observed that the public awareness has increased and the customers are looking for unethical practices followed by the hospitals or the doctors; although many a times the facts are different than belief. The growing public concern about the ethical conduct of healthcare professionals, specially the doctors, highlights the need to

incorporate clinical ethics in medical education including CMEs. The doctors are supposed to know and follow ethical principles while practicing [2].

Bioethics, being a new subject, at least for the medical fraternity in India needs lot of educational initiatives. The medical colleges are promoting bioethics teaching as a part of their curriculum after Medical Council of India (MCI) had directed the medical institutions to incorporate bioethics and ethical practices in their teaching schedule with the subject name of 'Attitude, Ethics and Communication' [3-4]. The new generation of doctors, who are just graduated or will be graduating in coming years, are sensitized toward ethics and ethical practices but the practicing doctors are still lacking the same. Many initiatives are started for the practicing doctors by the hospital with the help of external agencies like, UNESCO Chair in Bioethics (Haifa) [5]. To improve ethics quality in healthcare, hospitals need a way to identify whether ethical practices throughout the hospital are consistent with accepted ethics standards, norms, and expectations for the hospital and its employees.

Healthcare personnel frequently face ethically difficult situations in the course of their work and these issues cover a wide range of areas in clinical practice. One method to ensure that the doctors working in the hospital are following ethical behaviour and are aware about the ethical issues in the hospital is to incorporate the 'Ethics Knowledge and Practice by Doctors' in the performance appraisal [7]. This article dwells on this premise that by incorporating the 'Ethics' in performance appraisal of the doctors the ethical behaviour of the doctors could be positively impacted. To understand the applicability of ethics in performance appraisal it is helpful to understand the concept of performance appraisal and how the same is used for doctors. The subsequent paragraphs explained the same.

Performance appraisal is one of the important components in the rational and systematic process of human resource management. Performance appraisal can be defined as a performance review, performance evaluation and career development of employee. Performance appraisal is process of evaluating or reviewing the performance of an employee. It is the process of evaluation of how well employees perform their jobs and then communicating that information to the employee. Performance Appraisal is a formal systematic review and evaluation of individual or team performance. Performance in any type of industry is performed to evaluate the performance of employee, the need of training, the area of improvement, decision of increment and promotion, the parameters for selecting the right candidate with right qualities [7]. Performance Appraisal is a goal-oriented process directed towards ensuring that organization process is in place to maximize the productivity of employee, teams and ultimately, the organization. Performance Appraisal is a formal system of review and evaluating of individual or team task performance [8].

Without a reliable performance appraisal system, a human resource management system falls apart, resulting in the total waste of the valuable human assets a company has. Performance appraisal cannot be implemented successfully unless it is accepted by all concerned.

Performance Appraisal in A Hospital

Performance appraisal in a hospital should be done with primary motive to improve the quality of healthcare. Hospital is a different industry as compare to other service sector industries because of the variety of different skilled workers working in the hospital ranging from doctors to housekeeping staff. The major difference from the other industry is that hospital deals with the lives of the patient; so, for the satisfaction of the patients the employees' performance need to be up to the mark which require a regular performance appraisal. The hospital is accountable to patients and the community for providing quality services [9].

In the hospital patient is the most important person; therefore, all the employees of the hospital have to perform their duties in a way to get maximum patient satisfaction. It is equally essential to deal with patient and their relatives in the best possible manner to enhance the satisfaction. If the

performance of employees is appraised then it is very beneficial for both the employees and the management and easier to understand the current performance level and the area of improvements [10]. Also, performance appraisal helps to identify training needs of the employees so that they can be trained to improve their performance. This leads to customer satisfaction and overall organization development.

Performance appraisal in a hospital is very different from other industries in many ways. There are doctors from different specialties; allied healthcare staff like the nurses, pharmacy, technician; and administrative staff, like, the Reception, HR, Quality, and Finance department, of which the performance appraisal should be conducted. As there are different people with different duties and roles and responsibility so performance appraisal needs to be conducted in a different way and with different parameters to have effective evaluation and for better judgment of area to improve of both employee and hospital as a whole and the decision of judgment.

In a hospital the performance appraisal can be conducted by various methods. There are different types of staff working in the hospital with different roles and responsibility which need different type of evaluation system. The general administrative staff could be appraised by any of the established methods like 360 degree, Behaviourally Anchored Rating Scales, Management by Objectives (MBO) Method. The nursing staff, technicians, and doctors need specialized performance appraisal system. Competence mapping system is generally adopted for nursing staff and technicians as a performance appraisal tool [7,9]. For doctors specialized performance appraisals are tools are utilized all across the globe [10-11]. One of the newest and most comprehensive tool for doctors' performance appraisal is 'Ongoing Professional Practice Evaluation' (OPPE).

For conducting OPPE there are some parameters that need to be examined first. These parameters are relevant for the doctors to evaluate the performance in a right and a specific way, according to the complexity of the job. The parameters are Patient Care; Medical and clinical knowledge; Practice based learning and improvement; Interpersonal and Communication Skills; Professionalism and System based practice [12]. OPPE is ongoing data collection for performance appraisal for the doctors. After conducting OPPE, the need of FPPE arises if required by any employee. FPPE is a more focus evaluation on an employee. When OPPE is done, the need of FPPE arises. After performing OPPE, if the supervisor requires the need to focus on a specific area then FPPE is used. FPPE focuses on the area that needs to be focused more, the areas that require more attention and improvement.

OPPE at Maharaja Agrasen Hospital

Parameters	Aspects
Patient Care	10
Medical/Clinical Knowledge	8
Systems Based Practice	6
Practice Based Learning and Improvement	4
Interpersonal Communications	3
Professionalism	8
Total	39

Maharaja Agrasen Hospital (MAH) embraced OPPE after getting accreditation from JCI as a quality tool to enhance the capabilities of performance appraisal being done in the hospital.

Performance appraisal of doctors/consultants is one of the most difficult tasks to perform by administrators and HR department. The doctors' performance needs to be examined on different parameters which cannot be captured using prevalent performance appraisal tools; hence, MAH had decided to adopt OPPE to measure the performance of the doctors/consultants.

As mentioned above, there are six parameters on which the doctors are to be rated using different aspects. These are Patient Care; Medical and clinical knowledge; Practice based learning and improvement; Interpersonal and Communication Skills; Professionalism and System based practice. Each parameter consists of different aspects which are objectively measured using data from different audit reports and different departmental reports.

MAH decided to measure the performance of the doctors/consultants using ethical aspects also. For doing this, many ethical aspects are captured and being used to appraise the doctors' performance. Some of the key aspects are: Goal of Treatment Documented, Medication Errors due to Wrong Prescription, Medication Errors in OPD Prescription, Adverse Drug Event due to Prescription Error, Sentinel Event, Counselling done & documented, Compliance of Consents taken and financial counselling regarding the treatment cost. These aspects are captured and proper criterion is set to give marks to the data

Systems Based Practice Demonstrates both an understanding of the contexts and systems in which health care is provided, and the ability to apply this knowledge to improve and optimize health care.			
	Criteria	Data	Score
ALOS			
LAMA Cases			
Return to Casualty within 72 hrs			
Medication Errors due to Wrong Prescription			
Medication Errors in OPD Prescription			
Number of Referred Patients			

The objectivity of the data is maintained by using the same assessment criteria for all. One such example is discussed below:

Systems Based Practice Demonstrates both an understanding of the contexts and systems in which health care is provided, and the ability to apply this knowledge to improve and optimize health care		
	Criteria	Measure
ALOS	No Score	
LAMA Cases	No Score	
Medication Errors due to Wrong Prescription	1 to 10 Error = (-)1 More than 10 = (-)2	Number
Medication Errors in OPD Prescription	1 to 10 Error = (-)1 More than 10 = (-)2	Number
Number of Referred Patients	Patients Referred in one <u>year</u> Less than 5 = 0 5 to 10 = 1 11 to 20 = 2 21 to 30 = 3 31 to 40 = 4 More than 40 = 5	Number

CONCLUSION

Using this methodology, the assessment not only becomes objective but also focused and effective. The doctors are given a format of OPPE tool at the time of appointment so that they know how their work will be assessed. This way the doctors become more responsible and ethical practices are improved.

Further Scope of Research

This study used OPPE method and adopted the same after making necessary changes as per the requirements of MAH. The collection of data was specifically for one hospital. This research should be done on a larger scale with many hospitals participating in the research. Moreover, the research was a cross-sectional research; whereas, to determine the impact of including ethical practices in performance appraisal needs scientific tool to measure the ethical practice quantitatively. The tool to measure ethical practices quantitatively is still to be developed.

REFERENCES

1. Wynia MK. Performance measures for ethics quality. *Effective Clin Pract (ECP)* 1999;2(6):294-8.
2. Subramanian T, Mathai AK, Kumar N. Knowledge and practice of clinical ethics among healthcare providers in a government hospital, Chennai. *Indian J Med Ethics* 2013;2:96-100.
3. Zayapragassarazan Z, Kumar S, Kadambari D. Record Review of Feedback of Participants on Attitude, Ethics and Communication Module (AETCOM) Proposed by Medical Council of India (MCI). *Online Submission* 2019;11(1):43-8.
4. Arakal AK. MBBS syllabus revised after 21 years. *Deccan Chronicle*. [newspaper on the Internet] 2018 Nov Thursday [2018/11/8].
5. Deshpande SN. The UNESCO movement for bioethics in medical education and the Indian scenario. *Indian J Psychiatry* 2016;58(4):359-62.
6. Fanelli S, Lanza G, Zangrandi A. Competences management for improving performance in health organizations: The Niguarda Hospital in Milan. *Int J Health Qual Assur* 2018;31(4):337-49.
7. Edmonstone J. Appraising the state of performance appraisal. *Health Manpower Manage* 1996;22(6):9-13.
8. Vasset F, Marnburg E, Furunes T. Employees' perceptions of justice in performance appraisals. *Nurs Manage* 2010;17(2).
9. Coates G. Experiencing performance appraisal in a trust hospital. *Electr J Sociol* 2000;5(1).
10. Overeem K, Faber MJ, Arah OA, Elwyn G, Lombarts KM, Wollersheim HC, Grol RP. Doctor performance assessment in daily practise: does it help doctors or not? A systematic review. *Med Educ* 2007;41(11):1039-49.
11. Redman T, Snape E, Thompson D, Yan FK. Performance appraisal in an NHS hospital. *Hum Resource Manage J* 2000;10(1):48-55.
12. Woher JC. Ongoing Physician Practice Evaluation (OPPE): Challenges in Implementation in Japan—An Opinion. *J Japan Hosp Assoc* 2013;32:23-7.

Acknowledgements: Nil

Funding: Nil

Conflict of interest: None

Awareness of Patient's Rights Amongst the Teaching Faculty of Non-Medical Teaching Institutions in Belagavi

Rinku Porwal¹, Vishal Koulapur², Somshekhar Pujar³, Girish Moogi⁴, Kiran Patil⁵, Premalata Rotti⁶

¹Assistant Professor, Forensic Medicine & Toxicology, Shaikh Homoeopathic Medical College, Belagavi

²Associate Professor, Forensic Medicine & Toxicology, JN Medical College, Belagavi

³Associate Professor, Forensic Medicine & Toxicology, JN Medical College, Belagavi

⁴Principal and Head, Material Medica, Shaikh Homoeopathic Medical College, Belagavi

⁵Professor and Head, Organon of Medicine, Shaikh Homoeopathic Medical College, Belagavi

⁶Assistant Professor, Department Repertory, Shaikh Homoeopathic Medical College, Belagavi

Corresponding Author: Rinku Porwal

E-mail: romagporwal@gmail.com

ABSTRACT

Background: Patient self-sufficiency is affected by variety of factors, including illness, financial status and dependence. Many patients feel that they are not treated with due consideration and compassion and have no control towards their own care. This article reflects the study report about awareness of Patient's Right's proposed by Code of Ethics' Regulations, Medical Council of India⁹ and the code with the charter of patients' rights of the Consumer Guidance Society of India. With the objective - to assess the awareness of patient's rights amongst the teaching faculty of non-medical institutions in Belagavi at various cognitive domains.

Methodology: A cross sectional observational study was conducted amongst the teaching faculty of non-medical teaching institutions at Belagavi for a period of six months. Data was collected using a validated pre-tested questionnaire form. The collected data was analyzed with SPSS V.20 software and the Results were expressed as percentage using appropriate tables and figures.

Result: 300 participants completed the questionnaire. A large proportion of the faculty members (57.75%) are aware about their rights as patients. 29.83% of faculty members are partially aware about their rights as patients and 12.41% of the faculty members are unaware about their rights as patients.

Conclusion: This study summarizes the awareness of patient's right's is moderate in overall awareness and low in high cognitive domain. This emphasizes the need for formal education regarding Patient's Right's among the general population.

Keywords: Patient's rights, awareness.

INTRODUCTION

World Health Organization¹ has a mission to ensure 'health for all. The Universal Declaration of Human Rights⁸ (1948) international law of USA - recognizes 'the inherent dignity' and the 'equal rights of all members of the human family'. Based on this concept of the person, and the

fundamental dignity and equality of all human beings, the notion of patient rights was developed. In other words, what is owed to the patient as a human being, by physicians and by the state, took shape in large part thanks to this understanding of the basic rights of the person [1]. When we talk of the rights of a patient, we talk about the rights of a human being who is sick and suffering and needs help. It means that he has right to be provided the right kind of medical treatment by the right professionals at the right time using the right tools and techniques, with respect and human dignity, without any discrimination of any kind and much more than that. It means accountability of the health providers for ensuring all the above in terms of the laid down norms and standards of quality [2].

As derived from above, patient rights are rights which may be classified as either legal, those emanating from law, or human statements of desirable principles, such as the right to healthcare / right to be treated with dignity [3]. In India, unlike in many other countries, the rights of patients have not yet been spelt out in a legal form [2]. However, certain laws enacted from time-to-time and various judgments by the courts emanating from human rights, constitutional rights, civil rights, consumer rights and codes of ethics of medical and nursing profession have spelt out the obligations of the healthcare providers toward patients.

This has, indirectly, conferred certain rights on the patients, such as

- The right of access to healthcare and to be treated with respect and dignity (IMC Regulations).
- The right to be informed (COPRA).
- The right to consent and choice of care (IMC Regulations).
- The right to privacy and confidentiality (IMC Regulations).
- The right to choice of care and decision making.
- The right to redressal of grievances.

The legal declaration of patient rights can be traced in the Consumer Protection Act,[4] NABH Standards [5] addressing the issue of Patient Rights in Chapter 4: patient rights and education (PRE) and the American Hospital Association: A Patient's Bill of Rights [6].

Research about patients' rights, the degree to which these rights are exercised and respected will reveal the existing situation for the care givers including healthcare administrators to help with the policy making and management of the services. Thus, this investigation was to study the knowledge of the said population based on existing situation so as to reaffirm the said three basic needs, paving a clear path toward statutory compliance and healthy patient caregiver relationship.

Objective

To assess the awareness of patient Rights amongst the teaching faculty of non-medical teaching institutions in Belagavi city. (*At the level of high & low cognitive domains*)

METHODOLOGY

Type of research: Cross-sectional.

Research design: Survey method.

Tool: Pre tested validated questionnaire.

Sample size: 300.

Sampling method: Random sampling method.

Inclusion criteria:

- Non-medical institution Faculty
- Age 25-65yrs
- Education – Graduation and above

Exclusion criteria:

- Those that do not meet the inclusion criteria for the study
- Those that refuse to participate in the study

Written valid informed consent was obtained from all those that participated in the study. Data was collected on the basis of inclusion and exclusion criterion.

Data analysis: Through SPSS version 20 software and MS Excel.

RESULTS

Reliability test

A Reliability test for the questionnaire was conducted by **Cronbach's Alpha** - 0.829 i.e. the questionnaire is acceptable. (Acceptable range- >0.75)

Table 1 – Gender wise participation

		Frequency	Percent	Cumulative Percent
Gender	Female	181	60.3	60.3
	Male	119	39.7	100.0
	Total	300	100.0	

Table 2 – Age wise participation

Age	Range	Frequency	Percent	Cumulative Percent
	25-35 years	182	60.7	60.7
	36-55 years	104	34.7	95.3
	56-65 years	14	4.7	100.0
	Total	300	100.0	

Table 3 – Awareness based on the Questionnaire

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20
AWARE	254	244	192	205	185	200	179	192	222	176	202	141	159	93	118	95	165	142	134	167
PARTIALLY AWARE	41	50	88	69	90	73	92	73	68	92	77	120	97	124	116	122	95	105	109	89
UNAWARE	5	6	20	26	25	27	29	35	10	32	21	39	44	83	66	83	40	53	57	44

Table 4 – High cognitive domain questions

	Q3	Q4	Q12	Q13	Q14	Q15	Q16	Q19
AWARE	64%	68%	47%	53%	31%	39%	32%	45%
PARTIALLY AWARE	29%	23%	40%	32%	41%	38%	41%	36%
UNAWARE	7%	9%	13%	15%	28%	22%	28%	19%

Table 5 – Low cognitive domain questions

	Q1	Q2	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q17	Q18	Q20
AWARE	84%	81%	62%	67%	60%	64%	74%	59%	67%	55%	47%	56%
PARTIALLY AWARE	14%	17%	30%	24%	31%	24%	23%	31%	26%	32%	35%	30%
UNAWARE	2%	2%	8%	9%	10%	12%	3%	11%	7%	13%	18%	15%

Table 7 – Over All Analytical Result in Percentage

	OVER ALL ANALYTICAL RESULT	RESULT ON HIGH COGNITIVE DOMAIN QUESTIONS	RESULT ON LOW COGNITIVE DOMAIN QUESTIONS
AWARE	57.75%	47.33%	64.61%
PARTIALLY AWARE	29.83%	35.12%	26.19%
UNAWARE	12.41%	17.41%	9.08%

Table 8 - ANOVA Test for Significance

VARIABLES	HIGH COGNITIVE DOMAIN	LOW COGNITIVE DOMAIN	AT 5% LEVEL OF SIGNIFICANCE
AGE	p VALUE: 0.64 > 0.05	p VALUE: 0.655 > 0.05	INSIGNIFICANT
GENDER	p VALUE: 0.0025 < 0.05	p VALUE: 0.014 < 0.05	SIGNIFICANT

HYPOTHESIS A TESTING

- H0a- Age does not have an impact on high cognitive domain
- H1a- Age has an impact on High cognitive domain
- P value- 0.64 > 0.05 =accept h0a

HYPOTHESIS B TESTING

- H0b- gender does not have an impact on High cognitive domain
- H1b-gender has an impact on High cognitive domain
- P value- 0.0025 < 0.05 =reject h0

HYPOTHESIS C TESTING

- H0c- age does not have an impact on low cognitive domain
- H1c- age has an impact on Low cognitive domain
- P value- 0.655 > 0.05 =accept h0c

HYPOTHESIS D TESTING

- H0d- gender does not have an effect on Low cognitive domain
- H1d- gender has an effect on Low cognitive domain
- P value- 0.014 < 0.05 = reject h0d

Observations

- People are more aware of low cognitive domain questions.
- Age does not have an impact on high and low cognitive domain questions.
- Gender has an impact on both high and low cognitive domain questions.

DISCUSSION

No study was ever conducted on awareness of patient's rights at various domains. This study reveals a valid data about awareness of patient's rights at various cognitive domains amongst the teaching faculty of non-medical teaching institutions.

Limitation of study

The study about the awareness of patient's rights was conducted only on a small portion of educated people in Belagavi city.

CONCLUSION

This study summarizes the awareness of patient's right's and emphasizes the need for formal education regarding Patient's Right's among the general population.

Recommendation

Further studies are needed to analyse the awareness of patients' rights with a broader scope including various professionals and population at various domains.

REFERENCES

1. Assembly UG. Universal declaration of human rights. UN General Assembly 1948;302(2).
2. Joshi SK. Law and practice of medicine. New Delhi: Jaypee Brothers Medical Publishers (P) Ltd; 2010.
3. Pozgar, George D. Legal aspects of healthcare administration. Massachusetts: Jones and Bartlett Publishers; 2015.
4. Consumer Guidance Society of India[Internet]. Know your rights. Mumbai: CGSI[date unknown] [cited 2012 Sep 29].[about 10 screens]. Available from: <http://www.cgsiindia.org/knowyourrights.html>
5. National Accreditation Board for Hospitals and Healthcare Providers. Guide book to NABH Standards for Hospitals; 2016.
6. Cesar T, Hedrick S. ACHC: Accreditation for Home Care and Alternate Site Healthcare Services. Handbook of Home Health Care Administration. 2010.
7. Ghooi RB, Deshpande SR. Patients' rights in India: an ethical perspective. Indian J Med Ethics 2012;9(4):277-81.
8. Medical Council of India [Internet]. New Delhi: MCI; c2010. Code of Ethics Regulations, 2002. 2002 Mar 11[cited 2012 Sep 29]; [about 10 screens]. Available from: <http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx>

Acknowledgements

- *Final year students (2015 batch) of A.M. Shaikh Homoeopathic Medical College, Belagavi.*
- *Dr. Animesh Jain- Professor and Head, Department of Community Medicine, Kasturba Medical College, Mangalore.*
- *Dr. Deepak Tumari- M.D. (Homeopathy).*
- *Mr. Prayag Gokhle -Biostatistician.*

Financial grants for this paper: Nil

Conflict of interest: None

Original Research Paper

A Study to Assess the Awareness of Justice, Equality and Equity -Amongst Homeopathic Practitioners in Practice

Premalata Rotti¹, Kiran Patil², Girish Moogi³, Rinku Porwal⁴

¹Assistant Professor, Department Repertory

²Professor, Department Organon of Medicine

³Principal, Department Materia Medica

⁴Assistant Professor, Department Forensic Medicine

A.M. Shaikh Homoeopathic College, Belagavi, Karnataka.

Corresponding Author: Premalata Rotti

E-mail: drpremlatarotti@yahoo.in

ABSTRACT

Background: Homoeopathy, a holistic science deals with mental, emotional and physical symptoms of the patient during treatment. It demands intricate consultation with broad questions to elicit subjective symptoms and life experiences, enabling an understanding of the patient and connecting the psychological and physiological symptoms. This study aims to gain an in - depth understanding and perception about awareness, justice, equality; and equity amongst Homoeopathic practitioners while treating individual patients according to the set principles and give a fair, justified and equal opportunity to every individual who seeks help from homoeopathy.

Methodology: A cross sectional observational survey study was conducted amongst homoeopathic practitioners, teaching faculty and post graduate students of homoeopathic medical colleges of Belagavi for a period of 2 months. Data were collected using Self constructed questionnaire with Closed-end questions, validated by face validity and pilot study. The data was analyzed with item response theory and the results statistically procured with SPSS V.19 software, were interpreted for conclusion.

Result: 165 participants (of 200 questionnaires distributed) responded on awareness of justice, equality and equity amongst homoeopathic practitioners of which, 56.84% were aware, 29.15% were unaware and 14% were doubtful.

Conclusion: This survey encapsulates that 57% of homoeopathic practitioners were aware about justice equality and equity in practice. Of which- Justice - aware (56.6%), Unaware (37.87%), and doubtful (5.45%), Equality- aware (49%), Unaware (44.53%), and doubtful (6.36%) and Equity- aware (88.48%), Unaware (4.23%), and doubtful (7.27%).

Keywords: Justice, equality, equity, homoeopathy.

INTRODUCTION

Homoeopathy, a holistic science deals with mental, emotional and physical symptoms of the patient during treatment. It demands intricate consultation with broad questions to elicit subjective symptoms and life experiences, enabling an understanding of the patient and connecting the psychological and physiological symptoms. This study aims to gain an in-depth understanding and

perception about awareness, justice, equality; and equity amongst Homoeopathic practitioners while treating individual patients according to the set principles and give a fair, justified and equal opportunity to every individual who seeks help from homoeopathy.

Technical meaning of the commonly used terms in ethics

Equity: understand and give people *what they need* to enjoy full, healthy lives

Equality: in contrast, aims to ensure that everyone gets the same things in order to enjoy full, healthy lives [1].

Justice: fairness, righteousness. Justice is the morally fair and right state of everything [2].

Justice was about rightness (or “straightness”). To do justly was simply to act in conformity with an enlightened sense of moral righteousness [3].

According to World Health Organization [WHO], Homoeopathy is fastest growing & 2nd most widely used system in the world [4]. More than 70% of population believed that Homoeopathy is better than other systems, reason for that being no side effects, low cost of treatment, easy to take medicines which corresponds with the study of Singh and others [5].

According to the Government of India report, around 10% of India’s population depends solely on Homoeopathy for their healthcare [6]. Homeopathy is a gentle, complete system of natural medicine. Patients are treated as a whole - physically, mentally and emotionally - not just for the medical complaint they present with. Homeopaths observe that homeopathic medicine appears to stimulate the individual's natural ability to self-heal and reduce the intensity of their symptoms [7]. It is a low-cost, nontoxic system of medicine used by hundreds of millions of people worldwide [8]. In India, where homoeopathy is a national medical system.

India is arguably unique in the extent to which it has recognized homoeopathy as a legitimate system of medicine. Despite originating in Germany, the Indian government has bestowed it with the status of a national medical system [9]. Homoeopathy, if practiced properly, is cheaper, safer and effective for many ailments [10].

Objective

To explore an in-depth understanding and perception about awareness of justice, equality; and equity amongst Homoeopathic practitioners while treating individual patients.

METHODOLOGY

Type of research: A cross-sectional, observational survey on awareness about justice, equality and equity amongst homoeopathic practitioners in practice was conducted.

Duration of study: 2 months (June and August 2019.)

Tools used: Our study began with item response theory based on which a self-constructed questionnaire was developed by us and self-administered, which was filled by participants. The questionnaire was validated by face validity and pilot study. The questionnaire was in English. And was short and simple having ten closed end questions with appropriate options which took 10-15 min to complete. It included two sections;

- The first section consisted of individual's personal/social information (The personal/social information included name, age, gender, qualification, designation, department (for academicians) and institution details.)
- The second section contained ten questions regarding individuals’ awareness, practice, justice, equality and equity related questions.

Inclusion criteria: For our survey included all academicians from different homoeopathic medical colleges, practitioners and post graduate students in Belagavi district and participants of either sex included.

Statistical tool: Excel Spreadsheet. SPSS version V.19 was used for statistical analysis of the data.

RESULTS

A total of 200 questionnaires were distributed, and 165 were filled and returned

- Participation rate 82.5%

Table 1 - Awareness of justice, equality and equity amongst homoeopathic practitioners

	Justice	Equality	Equity
Yes	56.6%	49%	88.48%
No	37.87%	44.53%	4.23%

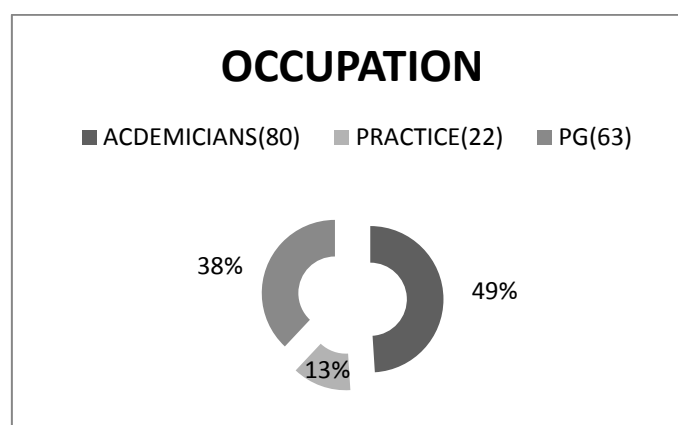
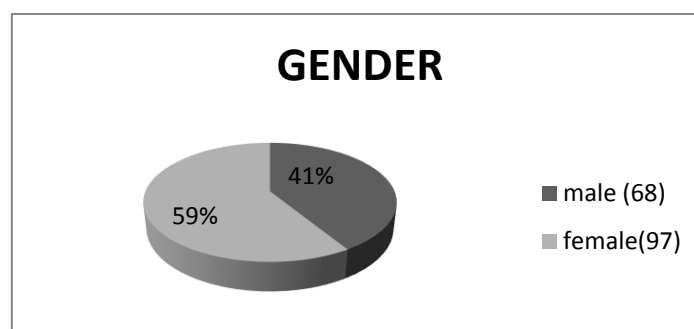
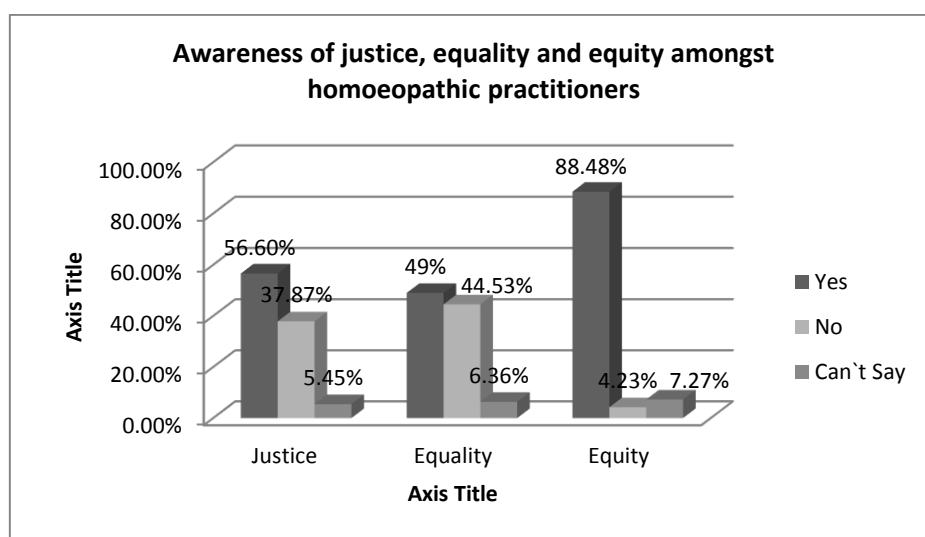


Table 2 – Responses of the participants

Topic	Yes	No	Can't say
Awareness	58	58	49
	68	53	44
Principles	26	74	65
	145	10	10
Justice	25	124	16
	162	1	2
Equality	150	2	13
	12	145	8
Equity	145	8	12
	147	6	12

The results were analysed using regression and correlated to awareness (independent variable) with-principles, justice, equality and equity (dependent variables). The observations were -

- Awareness has a correlation with principles (p value - 0.000549 < 0.05), the interpretation can be that being aware about homoeopathy can affect using principles in practice.
- Awareness has correlation with justice (p value - 0.0016 < 0.05), hence we observe that awareness about homoeopathy helps practitioners to treat patients judiciously.
- Awareness has no correlation with equality (p value - 0.254 > 0.05), being aware in no way helps a practitioner to treat every patient equally.
- Awareness has no correlation with equity (p value - 0.23 > 0.05), statistically we cannot correlate awareness about homoeopathy and equity during practice, on the contrary this study shows that 88.5% participants think that practitioners are treating every patient equitably.

DISCUSSION

Homeopathy seems well suited for use in rural areas where the Infrastructure, Equipment, and Drugs needed for Conventional Medicine cannot be provided [4].

In our study 56.6% (justice) of participants think the same. When we explored about equality in terms of treatment being economical for patients our study shows that 90% agree with this which is also corresponds with previous studies. Homoeopathic consultation happens as per law of individualization. Hahnemann in 6th edition of organon quotes - This individualizing examination of a case of disease, for which I shall only give in this place general directions, of which the practitioner will bear in mind only what is applicable for each individual case [11] (equity).

In our study questions about equity proves it where 88% participants agree with it.

Limitation of Study

The study was restricted to only 1 district.

CONCLUSION

This study is one of its unique kind where no such studies in the field of medical sciences, in particular homoeopathy were carried out in the past. The study revealed a valid data about the awareness about ethical practices amongst the homoeopathic practitioners.

Recommendation

An extensive study is required not only in Belagavi district but other parts too, to have a wider perspective. This study may be further explored to wider areas across state wise and nationwide to assess the ethical awareness amongst the medical practitioners of various streams.

REFERENCES

1. Folger R. Rethinking equity theory. In Justice in social relations (pp. 145-162). Springer, Boston, MA; 1986.
2. Deutsch M. Equity, equality, and need: What determines which value will be used as the basis of distributive justice ?. J Soc Issues 1975;31(3):137-49.
3. Kolm SC. Justice and equity. MIT Press; 2002.
4. Pandey MM, Rastogi S, Rawat AK. Indian traditional ayurvedic system of medicine and nutritional supplementation. Evidence Based Complementary and Alternative Medicine 2013;2013.
5. Sarangi MR, Pramanik A, Gupta J, Prasad R, Singh P, Shah M, Upadhyay AK, Jain S, Pandey A, Kumar A, Khurana A. A survey regarding awareness and beliefs about Homoeopathy among general population during Magh Mela at Allahabad, Uttar Pradesh, India. Indian J Res Homoeopathy 2019;13:12-21.
6. Prasad R. Homoeopathy booming in India. Lancet 2007;370(9600):1679-80.
7. Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. Ann Intern Med 2003;138(5):393-9.
8. Bornhöft G, Wolf U, von Ammon K, Righetti M, Maxion-Bergemann S, Baumgartner S, Thurneysen A, Matthiessen PF. Effectiveness, safety and cost-effectiveness of homeopathy in general practice—summarized health technology assessment. Complement Med Res 2006;13(2):19-29.
9. Singh B, Kumar M, Singh A. Evaluation of implementation status of national policy on Indian systems of medicine and homeopathy 2002: Stakeholders' perspective. Ancient Science of Life 2013;33(2):103.
10. Pustiglione M, Goldenstein E, Checinski YM. Homeopathy: a brief description of this medical specialty. Rev de Homeo 2017;80(3/4):1-5.
11. Hahnemann S. Organon of medicine. B. Jain Publishers; 2002.

Acknowledgements: Nil

Funding: Nil

Conflict of interest: None

Student Essay

Respect For Cultural Diversity

Sujata Devi¹

¹1st Year BSc Nursing student, NEIGRIHMS

Corresponding Author: Sujata Devi

E-mail: sujatadevi8472@gmail.com

Cultural diversity refers to the presence of diverse cultures in a society where people from different community irrespective of caste, creed, language, religion and race live together. The phrase 'Cultural Diversity' refers to having different cultures respect each other's differences. Respecting cultural diversity is to appreciate and value the diverse culture in a society. We should have a proper knowledge and understanding of the cultures which is not ours because it is necessary in order to bring about peace, harmony and love in the society.

Culture is the lens with which we evaluate everything around us. So, if we immerse ourselves in diverse culture, we get opportunities to interact and mingle with people from different background and learn from one another. We can build trust, love, respect and understanding across cultures thereby wiping out all the negative stereotypes and personal biases about different groups.

Studies show that diversity in education, particularly in college campuses improve the intellectual engagement, self-motivation, citizenship and cultural management and academic skills like critical thinking, problem solving and writing for students of all races. Interacting with diverse peers directly benefits students in expanding knowledge about their different worlds, beliefs, practices and more, making them better students, scholars, thinkers and citizens.

Culture shapes our identity and influences our behaviour and cultural diversity makes us accept, integrate and assimilate with other cultures. Cultural diversity has become very important in today's world. Diversity is not only important for adults but children should also be taught to accept and value different cultures by their parent, elders or teachers because today's children will be tomorrow's leaders.

India is a country where people of different cultures prevail and Indian culture is considered as the first and supreme culture of the world. There is a common saying about India that is, "Unity in Diversity". Furthermore, this diversity makes our country most vibrant and a more interesting place to live in as different cultures have contributed distinct flavours like different language skills, celebrate different festivals, have their own traditional attire, follow different food habits, possess different beliefs and faith. On the other hand, there are political parties in India which is becoming a major threat at present in order to create diversity amongst us for the sake of their personal interest but we should not come under their jurisdiction.

We should respect all culture and give our identity as "Indian". Concerned authorities should arrange programme such as National Integration Programme, fancy dress competition, etc so that people find it interesting and at the same time come to know about various culture. Reading simply cannot create such consciousness until it is implemented practically such programme will not only create respect for cultural diversity but will also improve their communication skill, enhance collaboration with different people. Thus bringing out unity through diversity.

Respecting cultural diversity imbues in us a feeling of mutual understanding and respect for someone from a different cultural background. It generates a feeling of brotherhood across diverse cultures.

In today's world, if we all are able to respect and know about other cultures and respect their values and beliefs, life would be easier for most of us and we can learn a lot of good things from each other and enrich our lives. Cultural diversity supports the idea that every person can make a unique and positive contribution to the larger society because of their differences. So, in order to build a healthy and peaceful society, every individual should take initiatives and participate in the establishment of a society, community, country or world on a large scale, where diversity in culture is recognised and respected, various cultural ideas are acknowledged and valued, contributions from all groups are encouraged and differences are celebrated.

Winner of the Third Prize – Essay Competition held at NEIGRIHMS, Shillong on the occasion of World Bioethics Day 2019

Acknowledgements – Nil

Source of Funding – Nil

Conflict of Interest – Nil

Student Essay

Respect For Cultural Diversity

Rashmita Devi¹

¹3rd Year BSc Nursing student, NEIGRIHMS

Corresponding Author: Rashmita Devi

E-mail: catrash.shi22@gmail.com

“Diversity is the one thing we have in common, celebrate it everyday”

It is uncontroversial to call for respect for cultural diversity and recognition of pluralism in a globalized world today. At present, the world we live in comprises about 195 countries, 6500 languages and more than 5000 ethnic and cultural groups - making our world more wonderful and colourful, or is it otherwise? Is this diversity making our world a chaotic place? But before going into these controversies, what actually is culture?

Culture, is a “way of being”. It is often described as the combination of a body of knowledge, a body of belief. It is that which shapes our identity and influences our behaviour. Culture is the lens with which we evaluate everything around us - we evaluate what is proper or improper, normal or abnormal through our culture. When these cultural differences can be felt and appreciated and used to make our lives better, we often use them as standards to judge other cultures and these judgements could reach a level where people begin to discriminate against those whose ways of being are different from their own – essentially, we tend to fear which we do not understand.

Importance of respect for cultural diversity in healthcare system:

Cultural respect is critical to reducing health disparities and improving access to high quality of care and response to the needs of diverse patients. When developed and implemented as a framework, cultural respect enables systems, agencies and groups of professionals to function effectively to understand the needs of group accessing health information and healthcare

Cultural respect is also critical for achieving accuracy in medical research. Poor planning in medical research, planning that does not take into account principles for cultural respect may yield inaccurate results.

Respect for cultural diversity provides many benefits for healthcare professionals and healthcare organizations along with the patients. Social benefits include increased mutual respect between healthcare workers and patients, increased trust and promotion of patient responsibility and empowerment in their own healthcare. When patients feel heard and understood by their healthcare provider, they are more likely to participate in preventive healthcare and less likely to miss health appointments. This can reduce medical errors and related legal costs for healthcare facilities and it can improve health outcomes for patients. Ultimately, a culturally competent organization can help reduce health disparities among patient-population, which is still a common problem today.

Lastly, cultural diversity supports the idea that every person can make a unique and positive contribution to the larger society because of, rather than their cultural differences. Imagine a place where diversity is recognized and respected; various cultural ideas are acknowledged and valued; contributions from all groups are encouraged; people are empowered to achieve their full potential; and differences are celebrated. So, the ‘take-home’ message is to look for ways to take advantage of linguistic and cultural diversity, rather than to treat this diversity as a problem.

As goes the saying from **Nelson Mandela** –

*“No one is born hating another person because of the colour of his skin,
or his background, or his religion.
people must learn to hate, and if
they can learn to hate,
they can be taught to love,
for love comes more naturally
to the human heart than its opposite.”*

**Winner of the Second Prize – Essay Competition held at NEIGRIHMS, Shillong on the
occasion of World Bioethics Day 2019**

*Acknowledgements – Nil
Source of Funding – Nil
Conflict of Interest – Nil*

Student Essay

Respect for cultural diversity

Ibajoplin Mary Kharkongor¹

¹2nd Year BSc Nursing student, NEIGRIHMS

Corresponding Author: Ibajoplin Mary Kharkongor

E-mail: Joplin267@gmail.com

“We have become not a melting pot but a beautiful mosaic. Different people, different beliefs, different yearnings, different hopes, different dreams.”

Jimmy Carter greatly depicts that there is beauty in our diversity.

Cultural diversity refers to the quality of diverse or different cultures in the society or nation as a whole. It is one that prospers from distinctiveness because they bring something magnificent to the societal table. We do not think nor solve problems in a similar way. Neither do we create the same – and that is exactly what makes diversity so essential and valuable. However, a question arises of “how can we attain or get there?” The answer is simple – “Respect for Cultural Diversity”.

The fight for cultural diversity is one our nation has toiled over since its conception. Struggling over how to accept and integrate a wide variety of beliefs, opinions, religions and outlooks, many groups in the nation have historically chosen to sequester themselves instead. Rather than a melting pot where cultures mixed, evolved, learned from each other and grew, we had a segregated society where groups stayed in their place and never ventured into enemy territory.

“No culture can live if it attempts to be exclusive” – Mahatma Gandhi.

Diversity is what brings colours to our world. The mindset that thinks that betterment is possible only by sticking to its own culture and thus refusing to mix with others lacks respect for diversity. Respect for cultural diversity enables us to embrace our differences. We live in a world of vivid colours and traditions, of differences and similarities, each equally beautiful and unique and thus by embracing variations we learn and inculcate peace and humanity.

Respect for this diversity simply means looking beyond all cultural practices, race, religion and each and every difference and for once stand as a single human race as said by Kofi Annan – *“We may have different religions, different languages, different coloured skin, but we all belong to one human race”*, this reminding us of humanity.

“Peace is not unity in similarity but unity in diversity, in the comparison and conciliation of differences” – Mikhail Gorbachev. These words remind us that peace can only be attained when we learn to appreciate the occurrence of differences of every group in society.

Every country, every community are strongly tied together by an intricate tapestry of individual values, norms and a specific history, so to understand their culture is to understand and respect them. Speaking to a person in a way which is sensitive to their own distinct, unique culture enables a brand to not only elicit the intended emotional response through branded communications, but also shows that the brand can be trusted to understand their consumer.

Last but not least, *“A nation’s culture resides in the hearts and in the soul of its people”* – Mahatma Gandhi.

These words flash the truth that cultural diversity lies in our hearts and once we can visualize the joy of it, we can learn to respect and celebrate our cultural differences.

Winner of the First Prize – Essay Competition held at NEIGRIHMS, Shillong on the occasion of World Bioethics Day 2019

Acknowledgements – Nil

Source of Funding – Nil

Conflict of Interest – Nil

Ethical Issues at the Beginning of Life

Padmaja Kanchi¹, Subodh Kanchi²

¹Associate Professor, Department of Community Medicine, Terna Medical College & TSHRC, Nerul

²Professor & Head, Department of Pharmacology, Vedantaa Institute of Medical Sciences, Dahanu

Corresponding Author: Padmaja Kanchi

E-mail: padmamddph@gmail.com

Welcoming the bundle of joy is not a cakewalk for everyone. This is true, in case of, illegitimate child, foetus with congenital anomaly, twin pregnancy, seriously ill child or risk involved with mother's health. In such cases, continuation of pregnancy and welcoming the new life involves ethical dilemma.

Here, we are touching upon the ethical issues in such cases.

Illegitimate Child

Women who have given birth under such circumstances are often subjected to violence at the hands of their families; and may even become victims of so-called honour killings and may face consequent punishments, including stoning [1-2]. Teenage pregnancy is an issue and women face physical and mental trauma and huge social disastrous embarrassment in India.

Serious Conditions of Foetus

When we think in the point of view of *pro-life*, it is the right of an unborn child, as foetus is a human. Hence, the foetus has the rights to live. But, in case of serious conditions, like, serious congenital anomaly, twin pregnancy with one of the foetuses is dead risking the mother's life or any other medical condition affecting mother's health abortion is mandatory [3-4].

Abortion prioritizes mother's right to life and personal choices regarding her body, health and family. It also highlights the concern for the welfare of the child, concern for the life of the mother and concern for the future of the society [5].

Principle of Double Effect

Therapeutic Abortion or MTP could become unavoidable *when mother's life is in danger, and this action is defended by the Principle of Double Effect*.

The doctrine (or principle) of double effect is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side effect of promoting some good end. According to the principle of double effect, sometimes it is permissible to cause a harm as a side effect (or "double effect") of bringing about a good result even though it would not be permissible to cause such a harm as a means to bringing about the same good end [6].

For Example: In Tubal Ectopic Pregnancy, when the foetus develops in the fallopian tube instead of the uterus, mother's life would be in danger from tubal rupture as it does not support the growing foetus. Tubal rupture is a medical emergency and can cause maternal death from sudden, massive internal bleeding and the foetus will also not survive.

Journey of Abortion laws in India

August 10, 1971: The Medical Termination of Pregnancy (MTP) Act was passed which legalised abortion.

December 18, 2002: The MTP Act was amended. The law of abortion was decentralised and penal sanctions were added for unapproved abortions that led to the formulation of MTP rules in 2003. These rules increase access for women, especially in the private health sector.

January 22, 2018: MTP Amendment Bill, 2018, was introduced in the Lok Sabha with the demand to substitute the 20 weeks duration with 24 weeks and added that it should be raised to 27 weeks in case of a rape survivor.

May 29, 2019: Petition filed at the Supreme court by Swati Agarwal, Garima Sekseria and Prachi Vats also challenged the 20-week gestation limit saying that advancements in science and technology has made it possible to terminate pregnancies at later stages.

May 26, 2019: PIL filed by Amit Sahni in the Delhi High Court asking to raise the 20 weeks limit to 24 weeks.

August 2, 2019: Affidavit submitted by the Union Health Ministry in response to the PIL filed by Amit Sahni. The affidavit stated that draft MTP Amendment bill, 2019 has been sent for inter-ministerial discussion.

August 6, 2019: Supreme Court issues a notice to the Centre seeking its response to the PIL filed by Swati Agarwal, Garima Sekseria and Prachi Vats [7].

Ethical Concern

Some of the ethical concerns are discussed below

1. Can woman demand abortion as her right?

Suitable reason and consent for medical termination of pregnancy must be documented according to the MTP Act. Only married women may use “failure of contraception” as grounds for termination of pregnancy [8].

2. Can a Doctor refuse to conduct a termination of pregnancy if it is against his conscience?

According to IMC Regulations 2002, Chapter 7.15 [9], the RMP shall not refuse on religious grounds alone, unless he feels himself incompetent to do so.

In reality, the doctor is allowed reasonable autonomy in clinical practice as MTP must take place in a hospital registered for the purpose [8].

On therapeutic abortion, the World Medical Association (WMA) acknowledges the diversity of opinion and concludes, that it is a matter of individual conviction, and conscience must be respected.

3. If mother requests MTP, can father object the procedure?

By law, the autonomy of the mother takes precedence over the father, in medical termination of pregnancy. The father cannot prevent a valid termination of pregnancy if the woman consented for it neither he can prevail on the doctor to conduct the MTP when the woman has not given the consent.

If MTP is critical for woman's health or survival, it is the doctor's duty to convince the husband and family members in the best interest of the patient.

Coming to the edge

In the past 25 years, our society has overcome longstanding taboos and repugnance to accept test-tube fertilization, commercial sperm-banking, surrogate motherhood, abortion on demand within legal limit, exploitation of foetal tissue, patenting of living human tissue, ... the deliberate generation of human beings to serve as transplant donors-not to speak of massive changes in the culture regarding shame, privacy, and exposure. Perhaps more worrisome than the changes themselves is the coarsening of sensibilities and attitudes, and the irreversible effects on our imaginations and the way we conceive of ourselves. For there is a sad irony.... We expend enormous energy to preserve and prolong bodily life, but in the process, our embodied life is stripped of its gravity and much of its dignity. This is, in a word, progress as tragedy [10-11].

Conclusion

In the nutshell, there is plethora of complicated ethical issues when it comes to the beginning of life. A doctor has to follow his conscience and to the best interest of patient.

REFERENCES

1. Gill AK, Strange C, Roberts K. Honour killing and violence. United Kingdom: Palgrave Macmillan; 2014.
2. IMAFIDON JO. RETENTION OF DEATH PENALTY UNDER THE NIGERIAN LEGAL.
3. Birchfield L, Corsi J. The right to life is the right to food: People's Union for Civil Liberties v. Union of India & others. Human Rights Brief 2010;17(3):3.
4. Mpinga EK, London L, Chastonay P. Health and human rights: epistemological status and perspectives of development. Med Health Care Philos 2011;14(3):237-47.
5. Beauchamp TL, Childress JF. Principles of biomedical ethics. Oxford University Press, USA; 2001.
6. McIntyre A. Doctrine of Double Effect In EN Zalta.
7. Gupta R. Abortion in India: Experts call for changes. Down To Earth [Internet]. 2019 Aug 28
8. Timms O. Bio-Medical Ethics-E-Book. Elsevier Health Sciences; 2016.
9. Jesani A. Professional codes, dual loyalties and the spotlight on corruption. Indian J Med Ethics 2014;11(3):134-6.
10. Malhotra A, Menahem S, Gillam L. Ethical issues in fetal management: a cardiac perspective. Int J Pediatr 2010;2010.
11. President's Council on Bioethics (US). Human cloning and human dignity: An ethical inquiry. President's Council on Bioethics; 2002.

Acknowledgements – Nil

Source of Funding – Nil

Conflict of Interest – Nil

Ethical Viewpoint Paper

Ethics In Radiology

Khalid Ahmad¹

¹Head/Founder Bioethics UNESCO, Nodal Unit-Afghanistan, Director of International Relationship, Mirwais Neeka Institute of Higher Education, Kandahar, Afghanistan and Honorary Physician at Consulate General of the Islamic Republic of Afghanistan, Mumbai.

Corresponding Author: Khalid Ahmad

E-mail: drkhahmad@gmail.com

Introduction

The term medical ethics was first coined in the year 1803 by an English author and physician Thomas Percival where the roles and duties of doctors within the medical field are published. With changing time, changes were made in the code of medical ethics.

Basic Ethical Principles

Autonomy: It is a person's self-reliance, independence, liberty, rights, privacy, freedom. It is the right of a patient to refuse or choose their treatment. A patient has a full right to make decision regarding health care.

Beneficence: Being kind, doing good work and charity. Health care provider should develop skills and knowledge, get trained with any new research or development in their required field so that they should act in the best interest of the patient.

Non-maleficence: The doctor should not be the cause of harm to the patient or the society, and they should promote good. • Justice- Treatments should be made available equally to everyone.

Veracity: Duty to tell the truth, and avoid deception except special, or exceptional cases.

Fidelity: Strict observance of duties and faithfulness to others.

Sources of Ethics

- Science
- Culture
- Religion
- Experience
- History

Ethics is derived from Greek word *ethos* meaning custom, habit, character, or disposition. It is the system or code of conduct and morals advocated by an individual or group or the study of acceptable conducts and moral judgement. Biomedical ethics is the branch of ethics dealing with dilemmas faced by medical professionals, patients and their families and friends.

A code of ethics presents a framework for a systematic examination of beliefs that may lead to an understanding of personal and professional morality and responsibility.

In a medical profession, the relationship which a patient shares with the doctor is the core part of the health care system, and it forms an important foundation of medical ethics. But unfortunately, this relationship is becoming weaker with each passing day and so often these days we see and read in newspapers that doctors are beaten by patients relative and the working environment for a doctor, which should be safe becomes scary. It becomes difficult for doctors to effectively treat the patient in such working condition where they are threatened for their own safety. Thus, it becomes

necessary on part of both the doctor and patient to come together and work towards maintaining a healthy relationship in the following ways:

1. The doctors should try to establish a good rapport with the patient, as this will develop trust on the doctor and the patient will give complete and important information about his illness during history taking, which will help in accurate diagnosis and better treatment of the patient and it will save time and resources.
2. The doctors in this technologically advanced age, must give sufficient time for each patient, to understand them and their illness, be kind and compassionate towards them, it will automatically allow the patient to confide on the doctor.
3. The doctor should provide all the information and options which the patient and the family members should know, take consent whenever required, take opinion from colleagues when needed for the betterment of patient's health. It is observed that a patient can receive best care by the doctor and health care system, if they work ethically.

Ethics between Doctor's Relationships

As a person in medical field, we are taught a lot of subjects dealing with diagnosis and treatment of the patient, but the basic code of conduct how we as a doctor should behave with each other is hardly given due importance. Dr. F. Udwadia, stated that "good teaching, though concentrating on essentials, must question dogma, must arouse and encourage an attitude of enquiry and thirst of knowledge and serve as a stimulus for further study. Above all, teaching must be imbued with an ethical slant." A doctor must always be a student, so they must learn from each other be it a senior or junior, because teaching can mold your minds with knowledge and experience. Lately we have heard of the shocking news of a young doctor committing suicide at workplace became the highlight everywhere. Doctors of today are beaten to death, live in overcrowded and filthy rooms, long working hours with insufficient sleep, underpaid and overworked. How many more doctors we have to lose before we start taking mental health and workplace harassment seriously and work towards it. These are creamy layer of the society who sacrificed a lot, fought all odds to survive the long duration of under-graduation, hectic internship, post-graduation, and super specialization, and yet after all these years of struggle they chose to end their lives where they know how precious a life is. So yes, doctors are not weak, they have endured a lot of struggles and patience.

We, doctors have been trained to give the best treatment to our patients but we are not giving our best behaviour to our colleagues. We leave our home and loved ones, some change city, some states, some even change their country to become a good doctor. We make hospitals our home, so why can't our colleagues and fellow residents and seniors become our family and support us and guide us whenever needed. I feel in such situation even though we are working non-stop, but we can be at mental ease with no pressure of seniors. Seriously, there was a time this profession was considered best and noble and people had high regard for them some even considered doctors as God. But these days doctors are not even considered human, people are losing their trusts on doctors gradually. This is a very sad phase in our profession and we should do as a whole medical community to safeguard our profession, and bring the respect and trust back to our profession before it is too late.

Professional Ethics

Professional ethics deals with "rightness and wrongness" of an act or behaviour as compared with natural reasons. Professional behaviour is defined by professional standards of conduct and scope of practice in their respective field.

Why is Ethics Important for the Radiologist ?

A Radiologist has to focus on the image which is behind the patient rather than spending time directly interacting with the patient like the other physicians. As the primary reader of medical images, a radiologist provide advice which are meant for the well-being of the patient, but the main role of the radiologist is informing about these results to the physician for providing the best care

to the patient. A radiologist when receives a request from another physician to perform an imaging study or perform a procedure on the patient, he becomes a part of the patient's medical team. Thus, being a member of the team involving in the treatment of the patient is crucial as accurate imaging and diagnosis depends on the radiologist.

Radiology is a specialized and one of the important branches of medicine where imaging technologies are used to diagnose and treat patients. Just like doctors from other specialization, the radiologists can also be liable to claims of malpractice caused due to diagnostic errors. With the development and advancement of technology, the role of a radiologist in the clinical management is increasing, so is the importance of radiological intervention in patient management. A radiologist is known as "Doctor's doctor" because a physician refers the patient to a radiologist for final diagnosis and confirmation. Thus, medical ethics should be considered an important part in the field of radiology and must be a part of training for the residents which can further help in patient management.

In order to safeguard the health of the patient at accurate time and help other medical professional by correct and timely diagnosis, we should establish a strong medical ethics through continuous education and self-practice. Radiologists should get involved where ever necessary with the patient to guide and give options in difficult decision making about the health care. Ethics in radiology and in medical profession will have a great impact on the patient and health care system in the long run.

The Role of A Radiologist as a Consultant

Whenever an imaging study is advised, a radiologist must ask whether exposure to radiation is necessary. Unnecessary imaging should be avoided, where the physician can treat the patient based on the clinical sign and symptoms and come to a diagnosis. It should not be done for financial gain, as the treatment itself is not affordable for majority of the population, especially people residing in the developing country like India. When the outcome will not change the treatment plan, imaging should be avoided.

The radiologist and the concerned physician should discuss the patient's condition and decide whether imaging is useful or can be harmful for the patient in certain situations.

Many a times physicians order inappropriate or potentially harmful studies for many reasons varying from the urgency to emergency, all the physicians not always have knowledge about imaging or have incomplete understanding of radiation exposure and its risk to vulnerable group such as pregnant women and children. In such cases the radiologist should discuss the case with the physician.

Basic Ethical Principles for a Radiologist

- A radiologist must conduct themselves in a professional manner, respond to the patient and support colleagues and help in providing ethical and quality patient care.
- A radiologist should avoid unnecessary radiological tests and radiation exposures.
- Good quality and updated radiological imaging machine and modalities which will directly decrease exposure to radiation.
- A radiologist must deliver patient care and services without any discrimination on the basis of sex, race, creed, religion, or socioeconomical status.
- A radiologist assesses situations, exercise care, discipline, and judgement, assures responsibility for professional decisions, and must act in the best interest of the patient.
- A radiologist must always take consent and explain procedures to be performed properly in a language understood by the patient.
- A radiologist must perform procedures according to the accepted standard of practice and demonstrate expertise in minimizing radiation exposure to the patient, self, and the working staffs.
- A radiologist must always practice ethical conduct appropriate to the profession and protect the patient's right to quality and a good radiological care.

- A radiologist must respect the confidence entrusted, respect the right to privacy by the patient and reveals confidential information only when required by law or to protect the welfare of the individual or the society.
- During examining a female patient, a male radiologist must make sure that the examination is carried out in presence of a female attendant.
- A radiologist must always continue to improve knowledge and skills by participating in educational and professional activities, attend conference to know the new changes and research in the field of radiology and get updated with new radiological techniques and studies. Must maintain a good relationship with each other and with other medical professionals.

Ethical Dilemma

All professional decisions in radiological technology and other health care practices involve a consideration of human values. Unethical behaviour that is clearly wrong, can be defined as ethical outrage. Ethical dilemmas occur when the correct choice is not clear and personal values may conflict, thus ethical dilemmas require ethical analysis.

Critical Thinking

Critical thinking is purposeful, self-regulatory judgement that results in the interpretation, analysis, evaluation, and inference. It allows imaging professionals to perform the following;

- Interpret and analyze ethical models and theories.
- Evaluate application of these models and theory to any given situation.
- Plan an appropriate course of action.

PNDT Act 1994

Pre-Conceptional and Pre-Natal Diagnostic Techniques (PCPNDT) Act, 1994 is an act formed by the Parliament of India in order to prevent female feticides and declining sex ratio. This act also banned pre-natal sex determination. It was noted that in the early 1990, ultrasound techniques were used very commonly in India. Indian family have a tendency of preferring male child over a female child, discrimination against women lead to usage of this ultrasound technique for their benefits in sex selection abortion. This harmful practice was reflected in the Indian census as the sex ratio was seen declining.

Provision in this act are as follow-

- This act prohibits sex selection, before or after conception.
- The pre-natal diagnostic techniques like amniocentesis and ultrasound can be used for detection of the following:
 1. Genetic and Chromosomal abnormalities
 2. Metabolic and Sex-linked disorders
 3. Congenital malformations
 4. Haemoglobinopathies
- The Radiologist should not perform ultrasound for the determination of sex of the fetus.
- The Radiologist should not communicate the sex of the fetus to the mother or family members by words, signs, or any other method.
- A copy of PCPNDT registration certificate and a booklet must be displayed in the waiting room and USG room.
- Form F must be completely filled with signed consent of the patient and the performing radiologist, and this form must be preserved at the clinic and online as well.
- Report must be submitted on the 5th of every month and all records need to be maintained for a minimum period of 2 years.
- If any person advertises for pre-natal and pre-conceptional sex determination facilities in form of any notice, article, documents, advertisement through media or print, can be imprisoned for three years and fined Rs.10,000.
- The PNDT Act has made it mandatory registration of all the diagnostic laboratories, all genetic counselling and laboratory centers and ultrasound clinics.

How to avoid Ethical Conflicts

- Understand the right thing to do in the right situations.
- Educate yourself and research professional standards of conduct and ethical principles as a guide.
- In certain situations, they are unavoidable, be respectful and rightful.

Conclusions

Ethics have become an important part for a radiologist today. In India, a radiologist must be cautious of radiological malpractice and PCPNDT Act. It is very important to have a basic information and knowledge about ethical issues so as to prevent oneself from professional liability in future. Professional ethics is specific to an occupation and defined by members of the profession at many levels. Ethical dilemma naturally occurs and requires thorough analysis. Medical professionals must possess a keen sense of the role that the human values can play in resolving ethical dilemmas that arises in professional practice, both in dealing with patients and other health professionals.

Acknowledgements – Nil

Source of Funding – Nil

Conflict of Interest – Nil

Scope of the Journal & Instructions to the Authors

Global Bioethics Enquiry is a journal of the UNESCO Chair in Bioethics and publishes reviews, original research papers, commentaries and case studies related to all issues in the field of Bioethics. Original viewpoints and narratives as well as poems in the field of bioethics are welcome. The journal also has a student section where articles in the field of bioethics written by undergraduate and post graduate students are considered.

THE EDITORIAL PROCESS

The manuscripts received shall be peer reviewed for possible publication with the understanding that they are being submitted to only this journal and not simultaneously submitted or accepted for publication elsewhere. The Editors shall review all submitted manuscripts initially. Manuscripts with scientific flaws or vague research designs may often be rejected. The journal will not return any unaccepted manuscripts. The reviewers shall review all papers in a blind review and convey their decision to the Editors. Within a period of 8-12 weeks, the contributors shall receive comments, need for corrections and notice regarding acceptance or rejection of the manuscript. Other journals appropriate for the paper may be suggested in some cases of rejection. Articles accepted would be copy edited for grammar, punctuation, print style, and proofs for correction shall be sent to the author prior to publication. Authors will be asked to sign a copyright form and undertaking for plagiarism in case of accepted manuscripts. Only upon receipt of corrected proofs from the authors and completion of all form required, will a paper be published in the journal.

TYPES OF ARTICLES

- **Original Research Papers or Article:** These papers should only include original research findings from planned research studies such as case-control series, surveys with high response rates, randomized controlled trials and treatment based intervention studies. Meta analyses shall be included in this section. The word limit is 6000 words excluding references and an abstract (structured format) of not more than 250 words with 4-6 key words.
- **Case Reports:** These should contain reports of new, interesting or rare cases of clinical significance or with implications for management. It could also include case reports where novel management methods were used. It has a word count of 1500 words with up to 15 references and an abstract of not more than 150 words.
- **Review Papers:** These are systematic and critical assessments of the literature which will be invited. Authors wishing to submit a review paper will have to contact the editor and seek permission for submission of the review. Only after permission has been sought will the article be accepted for peer review. The review article has a word limit of 8000 words and must be state of the art in every respect. Only invited reviews will be published. However exceptionally interesting topics even if uninvited when submitted may be considered.
- **Personal Subject Related Viewpoint:** These should be experience-based views and opinions on controversial issues that affect the profession. They could also be part of clinical problems that confront people in routine practice. The author should have sufficient experience or must have some unique personal experience based on the subject being considered. The word limit is 2500 words.

- **Announcements:** Information regarding conferences, meetings, courses, awards and other items likely to be of interest to readers should be submitted with the name and address of the person from whom additional information can be obtained (up to 200 words).
- **Book or Movie Review:** Exceptionally readable and good books and movies or documentaries which shall be academic and otherwise in the field of mental health shall be considered in this section. The word limit shall be 1500 words.
- **Poems:** Poems related to various themes in bioethics and allied sciences shall be considered based on their merit for this section.
- The journal is in evolution and newer concepts shall be considered from time to time.

SUBMISSION OF PAPERS

Send soft copy of the manuscript along with a covering letter in Microsoft Word 2007 or 2010. Name and designation of all authors with designation and name of the corresponding author must be mentioned. Copies of any permission(s) to reproduce published material, and to use illustrations or report information about identifiable people must accompany the manuscript.

All the manuscripts should be submitted via e-mail to the editor at email – russell.f.dsouza@gmail.com or avinashdes888@gmail.com

For online submission articles should be prepared in two files (first page file and article file). Images should be submitted separately.

First Page File: Prepare the title page, covering letter, acknowledgement, etc. using a word processor program. All information which can reveal your identity should be here. Use doc/pdf files. Please do not zip the files.

Article file: The main text of the article, beginning from Abstract till References (including tables) should be in this file. Do not include any information (such as acknowledgement, your names in page headers, etc.) in this file. Use doc/pdf files. Do not zip the files. Limit the file size to 400 kb. Do not incorporate images in the file. If file size is large, graphs can be submitted as images separately without incorporating them in the article file to reduce the size of the file.

Images and Tables: Submit good quality colour images. Each image should be less than 400 kb in size. Size of the image can be reduced by decreasing the actual height and width of the images (keep up to 800 pixels or 4 inches). All image formats (jpeg, tiff, gif, bmp, png, eps, etc.) are acceptable; jpeg is most suitable. Do not zip the files. All tables, figures and images must be duly labelled.

Copyright and Contributor's form: If the manuscript is submitted online, the contributors' form and copyright transfer form has to be submitted in original with the signatures of all the contributors within two weeks from submission. The scanned copyright form can also be submitted via e mail.

PREPARATION OF THE RESEARCH PAPER (MANUSCRIPT)

Please use A4 size (212 × 297 mm) on Microsoft Word, with margins of 1 inch from all the four sides. If sending a hard copy, type or print on only one side of the paper. Use double spacing throughout. Number pages consecutively, beginning with the title page. The language should be British English or American English.

Language

For all purposes the journal shall follow the language pattern of American English.

Title Page

1. Type of manuscript (Original/Review/Case etc)
2. The title of the article, which should be concise, but informative;
3. Running title or short title not more than 50 characters;
4. The name by which each contributor is known with institutional affiliation;
5. The name of the department(s) and institution(s) to which the work should be attributed;
6. The name, address, phone numbers, facsimile numbers and e-mail address of the contributor responsible for correspondence;
7. The total number of pages, photographs and word counts separately for abstract and for the text (excluding the references and abstract).
8. Acknowledgements: Specify contributions that need acknowledging but do not justify authorship, such as general support by a departmental chair and acknowledgments of technical, financial and material support. Also mention financial grants received or conflict of interest if any.
9. If the manuscript was presented as part at a meeting, the organisation, place, and exact date on which it was read along with mention of any award it may have received.

Abstract Page

The second page should carry the full title of the manuscript and an abstract (no more than the number of words already specified). For abstract we follow an unstructured abstract format that should not exceed 250 words. Below the abstract should provide 3 to 6 key words.

Text of the article

State the purpose of the article and summarize the rationale for the study or observation in Introduction. For case reports give incidence of similar cases in past. Describe the selection of the observational or experimental subjects clearly in Patients and Methods section. Identify the age, sex, and other important characteristics of the subjects. Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail. Give references to established methods, describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration. Reports of randomised clinical trials should be based on the **CONSORT statement** (<http://www.consort-statement.org>).

When reporting experiments on human subjects, procedures followed should be in accordance with the standards ethical committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000 (http://www.wma.net/e/policy/17-c_e.html). Do not use patients' names, initials, or hospital numbers, especially in illustrative material. Present the results in logical sequence in the text, tables, and illustrations. Do not repeat in the text all the data in the tables or illustrations; emphasise or summarise only important observations. Use standard guidelines for statistics (See *Ann Intern Med* 1988;108:266-73).

Emphasize the new and important aspects of the study and the conclusions that follow from them along with implications of the findings and their limitations in the Discussion section.

References

References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in brackets (). References cited only in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. The titles of journals should be abbreviated according to the style used in Index Medicus. Avoid using abstracts, unpublished observations, and personal communication as references. Please refer <http://www.icmje.org> for other types of references such as electronic media, newspaper items, etc.

1. Standard journal article: Seshadri L, George SS, Vasudevan B, Krishna S. Cervical intraepithelial neoplasia and human papilloma virus infection in renal transplant recipients. *Indian J Cancer* 2001;38:92-5.
2. List the first six contributors followed by et al.
3. Personal author(s): Ringsven MK, Bond D. Gerontology and leadership skills for nurses. 2nd ed. Albany (NY): Delmar Publishers; 1996.
4. Chapter in a book: Phillips SJ, Whisnant JP. Hypertension and stroke. In: Laragh JH, Brenner BM, editors. Hypertension: pathophysiology, diagnosis, and management. 2nd ed. New York: Raven Press; 1995. pp 465-78.

Tables

- Tables should be self-explanatory and should not duplicate textual material. Tables with more than 10 columns and 25 rows are not acceptable. Limit the number to minimum required.
- Number tables, in Arabic numerals, consecutively in the order of their first citation in the text and supply a brief title for each.
- Place explanatory matter in footnotes, not in the heading. Explain in footnotes all non-standard abbreviations that are used in each table. For footnotes use the following symbols, in this sequence: *, **, ***
- Obtain permission for all fully borrowed, adapted, and modified tables and provide a credit line in the footnote.

Illustrations (Figures)

- Submit three sets of sharp, glossy, un-mounted, colour photographic prints, with height of 4 inches and width of 6 inches.
- Computerised colour printouts are not acceptable.
- Figures should be numbered consecutively according to the order in which they have been first cited in the text.
- Each figure should have a label pasted on its back indicating the number of the figure, the running title, top of the figure and the legends of the figure. Do not write on the back of figures, scratch, or mark them by using paper clips.
- If a figure has been published, acknowledge the original source and submit written permission from the copyright holder to reproduce the material. A credit line should appear in the legend for figures for such figures.

Reprints

Journal does not provide any free printed reprints. Reprints can be purchased. Articles may be accessed online and pdf format will be sent to the authors. Contact the editor for any queries. Authors wishing to procure a hard copy of the journal may send their requests to the editor via email.

Plagiarism Policy

All articles will be examined by computer software for plagiarism. If it is found that a paper that has been submitted has been copied in parts or fully from an earlier published paper the authors will be duly informed and the paper may be rejected. Action against the erring authors may be taken as per recommendation of the editorial board.

Open Access Policy

The journal grants free, irrevocable, worldwide, perpetual right of access to and a license to copy, use, distribute, transmit, and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship.