WORLD JOURNAL OF ADVANCE HEALTHCARE RESEARCH

SJIF Impact Factor: 5.464

ISSN: 2457-0400
Volume: 6.
Issue: 7
Page N. 135-139
Year: 2022

Original Article www.wjahr.com

ETHICAL PRINCIPLES AND PRACTICES FOR RESEARCH INVOLVING PEOPLE WITH MENTAL ILLNESS IN INDONESIA: A PHENOMENOLOGICAL APPROACH

Dedi Kurniawan*[3], Lailatul Kodriyah[1,2] and Luthfiatul Mustafida[1]

[1]Department of Hospital Administration STIKes Kepanjen, Indonesia.
[2]Indonesia Hospital Management Faculty of Medicine, University of Brawijaya, Indonesia.
[3]Department of Nursing STIKes Kepanjen, Indonesia.

Received date: 20 May 2022 **Revised date:** 10 June 2022 **Accepted date:** 30 June 2022

***Corresponding Author: Dedi Kurniawan**
Department of Nursing STIKes Kepanjen, Indonesia.

INTRODUCTION

Research activities must adhere to a scientific attitude and principles of research ethics. Although the interventions carried out in research do not have risks that can harm or harm the research subjects, researchers need to consider socio-ethical aspects and uphold human dignity.[1] Research on mental health problems in Indonesia and globally is massive and complex. Basic health research.[2] shows that 11.6% of the adult population (over 15 years old) in Indonesia experience mental and emotional problems, and 0.46% have severe mental disorders.[3] With the high number of mental health problems that occur, of course, requires treatment and therapy solutions to overcome these problems. However, the survey data from WHO also shows that serious treatment gap. Between 35.5% to 50.3% of severe cases in developed countries and 76.3% to 85.4% in developing countries received no treatment in the last 12 months.[4] Therefore, research in the field of mental health is needed to continuously improve our knowledge of mental health and ultimately provide better health services for sufferers.

Advances in science and research during implementation of health services, raise their concerns about ethical issues. Concern about misuse in research is crucial considering that the current experimental health research methodology does not only focus on biomedicine but deals directly with humans. Althought studies designed with treatment that conduct studies of human subjects carry risks to these subjects. This risk is still justified because considered research is not solely due to the personal benefits felt by the researcher or their institution, but because of the benefits for the subjects in the research activities and the possible long-term benefits of knowledge in the world of health.[5]

Research involving subjects with mental illness is essential to improve the quality of handling mental disorders. However, it is crucial that people with mental illness become one of the vulnerable groups that have to be protect from adverse treatment during the research process. Two main things essential to provide special treatment to people with mental disorders participating as research subjects are the abillity of self decisions, and stigma or negative views about mental disorders.[6]

People with mental disorders are often stigmatized. Stigma and discrimination against people with mental disorders due to community labeling such as futile, effortless, and inferior. Poor ADL skills include a decrease in self-care ability such as health care, bathing, gowning, shopping, cooking, or caring for the environment. Interpersonal relationship problems due to decreased communication skills, ability to interact and wrong react to other people, and stigma related to bad occupational functions.[7]

According to these situations, patients with mental disorders who became research respondents must receive special attention. Various efforts have been chosen to reduce and protect against possible abuse and violations in the research process. Several rules and regulations have been chosen to regulate ethics in research. With this provision, this study can prevent violations and abuse of the rights and welfare of human subjects, both research subjects among health workers, patients and families, and the community. Through these efforts, it provides that human values are something fundamental as a guide in regulating all research involving human subjects, and protection for the rights and welfare of all human subjects against scientific experiments in research.[4]

The conflict between the need for rapid and efficient research aimed to find the best treatment answers for sufferers and the protection of humans who are the research participants has received serious attention since the last few decades. Research ethics was developed primarily to bridge the need to conduct research with the protection of the human being who is the subject. Both are essentials that must be done synergistically. Therefore, the ethical dilemma in research with human subjects is not a conflict between good and bad, but a competition between goodness, such as the merits of safe research, and the goodness of knowledge generated by research.[8] Therefore, the authors are interested in discussing ethical issues of research on the subject of mental patients. The aim of this study was to explore an ethical review of research on the subject of mental patients in Indonesia.

MATERIALS AND METHODS

The study design used was qualitative with an interpretive phenomenological approach. The data collecting using in-depth interviews with semi-structured interview guides involving eighteen mental health researcher who participated in this study. The aims of this study are to explore an ethical review of research on the subject of mental illness patients in Indonesia. Participants were interviewed individually and asked this single question: What are the ethical considerations of research involving patients with mental illness? Participant's descriptions were analyzed using Interpretive Phenomenology Analysis (IPA).

In total, 18 researchers have conducted research involving patients with mental illness. Prospective respondents were recruited after a screening process was carried out using the Science and Technology Index (SINTA). SINTA (http://sinta3.ristekdikti.go.id/) is a platform to measure science and technology development which was designed and developed by the Ministry of Research, Technology, and Higher Education of Indonesia. There were 5 mental health journals in the SINTA database. Henceforth, all of the articles that reviewed and identified the corresponding authors were contacted and recruited from each of those journals.

RESULTS

The characteristics of 18 participants are shown in Table 1. The majority of participants were female (n = 10, 55.56%), and 83.34% had completed Master’s or equivalent level of education. Only 12% of respondents interviewed had <5 years of experience, but a large percentage (88%) had mental health researchers experience for >5 years.

Table 1: Demographic characteristics of participants (n=18).

Characteristic	Number (*n*=12)	Percent (%)
Sex		
Male	8	44.44
Female	10	55.56
Age, years (mean): 40.6 (n=18)	N/A	N/A
Marital status		
Married	14	77.78
Single	4	22.22
Divorced	0	0
Not reported	0	0
Level of education		
Bachelor’s or equivalent level	0	0
Master’s or equivalent level	13	83.34
Doctoral or equivalent level	5	27.76
Not reported/ Not elsewhere classified	0	0
Years of work experience as mental health researchers 5.15 (n=18)	N/A	N/A

Table 2: Conceptual framework ethical principles and practices for research involving people with mental illness in Indonesia (n=18).

Respect for human dignity	Potential benefits of the research	Direct benefits that may result from participation
		Benefits to the general participant population
		General benefits of the research for society, science and humanity
Respect for privacy and confidentiality	The protection of participants’ privacy	Ensure access to the minimum amount of information necessary
	Keeping confidentiality data	Participants’ private information will be coded
		Participant identities will be disclosed as a result of this research
		Secure data and/or specimens for the research
Respect for justice and	The obligation to treat people fairly and	Research distributes benefits and burdens equitably or according to people's needs, abilities, contributions and free choices

inclusiveness	equitably(vulnerability)	
Balancing harms and benefits	Potential research risks or discomforts to participants	Information pitfalls (e.g., lack of confidentiality and/ or breach of confidentiality). Cerebral or emotional pitfalls (e.g., inflicting fear, pressure, confusion, guilt, lack of tone- regard, melancholy, once emotional gests). Social danger (e.g. social smirch, expatriation or viable expatriation), profitable danger (e.g. development or insurance). Bodily dangers or detriment (similar as fatigue, ache or pain, eventuality for harm, infection or demise, facet items and contraindications of the drugs or substance used in the observe). Criminal pitfalls (e.g. chance of execution, compulsory reporting). Inheritable sequestration pitfalls (e.g., stigmatization, tone- smirch, restricted coverage content material or employment openings, maternity crimes, and many others).
Informed Consent Process	Describe the informed consent process	How the essential elements of informed consent are communicated to individuals (e.g. Knowledgeable consent files, oral scripts, online statements, correspondence, and so forth.)
	Facilitate Understanding	Describe how the researcher will make certain that individuals understand all elements of studies participation (e.g., whether or not members will be requested or recommended to invite questions about the manner).
	Documentation and additional considerations	Describe how the researcher plans to document that each participant has provided informed consent and/or assent.
		Describe the capacity of the participant and their ability to assent.
		Describe how assent to participate will be obtained and documented.

Primary data: 2020

In-depth interviews with these participants emphasized five categories describing sources of researchers ethical considerations of research involving patients with mental illness. These ethical review provide a combination of intrinsic and extrinsic factors (Table 2).

DISCUSSION

Research on human subjects has two main things that make ethical protection for people with mental illness was crucial; the capacity to make decisions, and, the negative stigma about mental illness.[9] The capacity to make decisions is essential in the process of obtaining consent after valid informed consent. Consent after explanation (PSP) is a key research ethical principle that has existed since the Nuremberg Code (1948). In the Guidelines for Health Research Ethics in Indonesia, the issue of the capacity of people with mental illness and PSP also receives special attention and is contained in guideline 15.[10]

Decision-making capacity is a clinical term that is specific to describe the patient's clinical ability to make specific decisions. The capacity of people with mental illness has decreased because of the symptoms of mental illness themselves, and from a decrease in cognitive function.[11] Mental illness can affect thought processes. For example people with depression who want to participate in research because they hope to die in the 'experimental' process, anxiety sufferers who tend to refuse and worry excessively, and people with psychosis whose actions and thoughts due to delusions and hallucinations. The cognitive function can occur due to chronic and ongoing symptoms, as well as due to long-lasting social isolation.[11] The problem of stigma (negative views and discriminatory attitudes from society) towards people with mental illness.

Frequenly, patients with mental illness who are the object of research, their fate is no longer known after the completed research with unclear results. Especially true for people from certain groups (different races, ethnicities, prisoners of war, etc.). The number of ethical codes developed to provide guidance and establish principles for addressing these ethical issues. The first international document that became the main reference for research ethics was the Nuremberg Code which dealt with the criteria for participants and the conduct of research. It was later adopted by the United Nations General Assembly. The next development was the establishment of the Declaration of Helsinki by the World Medical Association on ethical considerations in biomedical research. Another document is the Belmont Report by the US National Human Protection Commission which describes how the principles apply to research practice.

Respect for human dignity

Ethics is the study of morality - systematic and careful reflection on morals and analysis of moral decisions and behavior.[12] Ethics deals with all aspects of human actions and decisions, so ethics is a broad and complex field of study with various branches and subdivisions.

Researchers want to remember the rights of topics to obtain wealthy statistics related to the path of studies and have the liberty to make alternatives and be free from coercion to participate in research sports (autonomy). Numerous actions associated with the principle of respecting human dignity are: the researcher prepares a topic consent shape (knowledgeable consent) which consists of an explanation of the advantages of the research, an explanation of the viable risks and inconveniences, acquired the blessings statistics, the state of the researcher being capable of answer any questions. The states approximately topics because of the studies tactics.[9,13] The viable letter of that topics being capable of withdraw at any time, and the guarantee of anonymity and confidentiality.

However, the subject's consent form is insufficient to protect themselves, especially for clinical research related to the differences in information and authority between researchers and subjects.[14] These weaknesses should be anticipated by the existence of research procedures.[15]

Respect for privacy and confidentiality

Anybody has fundamental character rights, inclusive of privateness and person freedom.[16] The outcome of this examine is the disclosure of statistics about the contributors, including non-public information. Meanwhile, not absolutely everyone wants to share their information with others, so researchers have to pay attention to those simple rights of people. Researchers are also no longer authorized to show statistics about a topic's call or deal with on questionnaires and measurement equipment to keep the anonymity and confidentiality of the challenge's identity. Researchers may additionally use coding (preliminary or identification range) instead of identification.[13,17]

Respect for justice and inclusiveness

The precept of justice has the connotation of openness and fairness. The standards of openness, studies is finished virtually, carefully, professionally, with humanity, and can pay interest to elements of accuracy, thoroughness, accuracy, intimacy, and psychological and spiritual feelings of research topics.[9,17] The studies surroundings is set thus to fulfill the principle of openness through the clarity of studies procedures. Justice has numerous theories, but the maximum important is how the blessings and burdens distribute the various contributors of the community group. The principle of justice emphasizes the volume to which studies rules provide advantages and dangers equitably or consistent with the needs, skills, contributions, and free picks of society.[13] For instance, in studies processes, researchers remember gender equality and individuals' rights to identical treatment before, throughout, and after participation in research.

Balancing harms and benefits

The studies process according to research methods and method to attain an superior gain for studies subjects and is probably generalized on the populace degree (beneficence). Researchers reduce the detrimental effect on the problem (non-maleficence).[10,16] But, the studies intervention has the capability to cause extra harm or strain, individuals ought to be excluded from research sports to save you injures, illness, misery, or death of the research challenge.

In the abstract, 'benefit' and 'harm' are simple enough words to understand.[10] When applied to research process, it's important to remember that every intervention involves both. The really tough part comes in understanding and balancing the benefits and harms of each intervention and communicating these to each participant, in the context of their vulnerable condition and their life experiences. This allows the researcher to practice both humanity and good evidence-based practice.

Informed Consent Process

Informed consent is the process of explaining research to potential participants to allow deciding to engage in research or not.[18] Its the basis for the protection of human rights. The three main elements of informed consent are competence, knowledge, and volunteerism.[10,18]

People with mental illness were inability to make decisions often encountered by researchers.[16] Therefore the consent of mental illness patients is represented by the family as the closest person to the patient. In the research context, human rights are vulnerable to be violated due to three main factors, intrinsic vulnerability (the mental condition of prospective participants), extrinsic vulnerability (the participant's environmental conditions), and relationship vulnerability (conditions of the relationship between participants and researchers or other participants).

Researchers must obtain participant consent to involve them in the study. The Human Rights Committee of the IFGO Ethics Committee (International Federation of Gynecology and Obstetrics) regulated the decision freely obtained without any pressure or inducement.[19] The research subject has explain the study aimed, clearly, and complete informations, and is delivered in easy language that clearly understood by the public and research subject.

The researcher must explain all information regarding the research process, and the benefits and risks that may arise. So that the research subject understands the explanation given. The participant might to repeat the informations given regarding the research to process. In addition, the research subjects signed the informed consent and those who were illiterate could put their thumbprints in front of the witnesses.

CONCLUSION

Research involving people with mental illness in Indonesia was developed primarily to bridge the research process by prioritizing the protection of human beings who are the subject. Research shows that five conceptual framework ethical principles and practices categories emerged from data analysis for research involving people with mental illness in Indonesia: (i) Respect for human dignity; (ii) Respect for privacy and confidentiality; (iii) Respect for justice and inclusiveness; (iv) Balancing harms and benefits; (v) Informed Consent Process. The findings suggest that each researcher has a unique way to approach and protect participants from the negative impact of research. In conclusion, the research lack of experience and sense of responsibility was a barrier to adherance ethical principles and practices involving people with mental illness in Indonesia research.

ACKNOWLEDGEMENT

The authors would like to thank the Office of Research and Publication (ORP) Kepanjen School of Health Sciences, Malang, Indonesia, for assisting in the language editing.

REFERENCES

1. Agasisti T, Cordero JM. The determinants of repetition rates in Europe: Early skills or subsequent parents' help? J Policy Model, 2017; 39: 129–46. https://doi.org/https://doi.org/10.1016/j.jpolmod.2016.07.002.
2. Riskesdas. Laporan Provinsi Sumatera Utara Riskesdas, 2018.
3. Megatsari H, Laksono AD, Ibad M, Herwanto YT, Sarweni KP, Geno RAP, et al. The community psychosocial burden during the COVID-19 pandemic in Indonesia. Heliyon, 2020; 6: e05136–e05136. https://doi.org/10.1016/j.heliyon.2020.e05136.
4. Demyttenaere K, Bruffaerts R, Posada-Villa J, Gasquet I, Kovess V, Lepine JP, et al. Prevalence, severity, and unmet need for treatment of mental disorders in the World Health Organization World Mental Health Surveys. JAMA, 2004; 291: 2581–90. https://doi.org/10.1001/jama.291.21.2581.
5. Effendi A, Fatimah AT, Amam A. Analisis Keefektifan Pembelajaran Matematika Online Di Masa Pandemi Covid-19. Teorema Teor Dan Ris Mat, 2021; 6. https://doi.org/10.25157/teorema.v6i2.5632.
6. Hilton NZ. The Role of Attitudes and Awareness in Anti-Violence Education. J Aggress, 2000; 221–38. https://doi.org/10.1300/J146v03n01_14.
7. Corrigan PW, Watson AC. Understanding the impact of stigma on people with mental illness. World Psychiatry, 2002; 1: 16–20.
8. Koide R, Lettenmeier M, Akenji L, Toivio V, Amellina A, Khodke A, et al. Lifestyle carbon footprints and changes in lifestyles to limit global warming to 1.5 °C, and ways forward for related research. Sustain Sci, 2021; 16: 2087–99. https://doi.org/10.1007/s11625-021-01018-6.
9. Ketefian S. Ethical considerations in research. Focus on vulnerable groups. Investig y Educ En Enferm, 2015; 33: 164–72. https://doi.org/10.17533/udea.iee.v33n1a19.
10. National Code of Health Research Ethics Committee of Nigeria. National Code of Health Research Ethics, 2007.
11. Kurniawan D, Kumalasari G, Fahrany F, Hardiyanto, Roesardhyati R. " What Does the Barriers of Being a Layperson in Community and Mental Health Mean ?" a Phenomenological Approach. Indones J Heal Care Manag (IJOHCM), 2021; 2: 10–7.
12. Godlee F. Balancing benefits and harms. BMJ, 2013; 346: 3666. https://doi.org/10.1136/bmj.f3666.
13. Van Wijk E, Harrison T. Managing ethical problems in qualitative research involving vulnerable populations, using a pilot study. Int J Qual Methods, 2013; 12: 570–86. https://doi.org/10.1177/160940691301200130.
14. Siriwardhana C, Sumathipala A, Siribaddana S, Samaraweera S, Abeysinghe N, Prince M, et al. Reducing the scarcity in mental health research from low and middle income countries: A success story from Sri Lanka. Int Rev Psychiatry, 2011; 23: 77–83. https://doi.org/10.3109/09540261.2010.545991.
15. Personal M, Archive R. Munich Personal RePEc Archive Qualitative Research Methodology in Social Sciences and Related Subjects Qualitative Research Methodology in Social Sciences and Related Subjects. J Econ Dev Environ People, 2018; 7: 23–48.
16. American Psychiatric Association's Task Force on Research Ethics. Ethical Principles and Practices for Research Involving Human Participants With Mental Illness, 2006.
17. Campi R, Amparore D, Checcucci E, Claps F, Teoh JYC, Serni S, et al. Enhanced Reader.pdf. Nature, 1997; 388: 539–47.
18. Nijhawan L, Janodia M, Muddukrishna B, Bhat K, Bairy K, Udupa N, et al. Informed consent: Issues and challenges. J Adv Pharm Technol Res, 2013; 4: 134–40. https://doi.org/10.4103/2231-4040.116779.
19. Zampas C. Legal and ethical standards for protecting women's human rights and the practice of conscientious objection in reproductive healthcare settings. Int J Gynecol Obstet, 2013; 123: S63–5. https://doi.org/10.1016/S0020-7292(13)60005-3.