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Asia Pacific Forum on Ethics & Social Justice
Asian Bioethics Association

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 2023 Asia Pacific Forum on Ethics & Social Justice Malaysia

PREFACE

The **'22nd Asian Bioethics Conference & Roundtable on Global Health Security'** is an annual international conference of the Asian Bioethics Association. This year's conference is organized by the Asia Pacific Forum on Ethics and Social Justice and hosted by the Centre for Bioethics and Humanities, International Medical Univers it y. The conference is also supported by the Faculty of Social Sciences & Humanit ies, Universiti Kebangsaan Malaysia, American University of Sovereign Nations (AUSN) and Eubios Ethics Institute.

This conference series has been held in many cities in the Asia Pacific since 1995. This includes cities like Beijing (China), Kobe, Tsukuba, Tokyo, Beppu & Kumamoto (Japan), Seoul and Gangnueng (South Korea), Sanliurfa (Turkey), Bangkok (Thailand), Yogyakarta (Indonesia), Tehran (Iran), NUS (Singapore), Taipei & Kaohsiung (Taiwan), Kuala Lumpur (Malaysia), Chennai (India), Manila (the Philippines), Kaohsiung (Taiwan), Dhaka (Bangladesh) dan the USA. This year's conference has drawn participation from 17 countries, which includes scholars from Thaila nd, Indonesia, the Philippines, India, Pakistan, Bangladesh, Nepal, Taiwan, Turkey, Japan, the United States, Sri Lanka, Macau, South Korea, Saudi Arabia and Malaysia. The conference also features a Roundtable on Global Health Security & Youth Ambassador Programme.

This conference covers a wide range of cross-disciplinary fields such as bioethics, medical sciences, new technologies, environmental ethics, social sciences, justice and

morality, and other ethics-related fields. This meeting will focus on the post-pandemic world and global health security. The field of bioethics continues to grow and evolve, encountering new challenges and issues that necessitate careful consideration and ethical analysis. This conference offers us a unique chance to gather, share our knowledge and experiences, and engage in meaningful discussions about the most pressing ethical issues of our time.

ASSOC. PROF. DR RAVICHANDRAN MOORTHY
President, Asian Bioethics Association.
Organizing Chairperson,
22nd Asian Bioethics Conference & Roundtable on Global Health Security'
15th –17th May 2023.

7. TRANSFORMATION OF NOMENCLATURE: LAYPERSON TO PEOPLE REPRESENTATIVES IN IRB

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Abstract

Membership of a layperson is mandatory in the research ethics committee. According to World Health Organization (WHO), still there is a quorum of an ethics commit tee meeting (EC), however, the EC meeting should be adjourned if the absentee of a lay person. So layperson is a very important position in the EC. Layperson is a person whose primary area of interest is not scientific, however, they share their insight into the research to protect the research participants. Actually who and what lay members represent on ethics committees remains unclear, and the question of what laypersons mean what is their educational status, and what is their role in the research ethics committee is also not clear. In some Institution Review Boards (IRB)s, use the term public representatives instead of lay persons. Moreover, the education qualification of the layperson is as high as Ph.D. This paper argues why not the nomenclature shou ld change to a public representative instead of the layperson in the IRBs. If the

nomenclature is changed that establishes their positive image in the IRB and also increases their self of security, respect, and self-esteem.

Keyword: Layperson, Nomenclature, IRB, EC

Introduction

IRB constitutes scientific and non-scientific members. Non-scientific members may be lawyers, philosophers, social scientists, religious persons, journalists, and laypersons, etc. Prioritizing the non-scientists in the IRB is to maintain professional credibilit y, promote respect for the IRB's decision, and build trust in the general public regarding the healthcare research system (Kaye 2021). Therefore, diverse forms of memberships enhance solidarity and communal decision-making and promote safeguarding the rights and welfare of human participants (Kaye 2021).

However, lawyers, religious persons, and social scientists have a particular role and responsibility in IRB to clarify the things clear in respect of legal, religious, and societal perspectives of the research (Klitzman 2012). Conversely, the layperson views the protocol and potential conduct of the study to safeguard the research participants from the participants' perspective (Tripathi 2012). By definition, layman is a person who is not performing or educated in any field of medicine or paramedical discipline (Robinson, 1991). Nevertheless, up to now, many of the research ideas and clinica l information reporting have been done by the layman in the IRB (Garfield et al., 2016). According to WHO if there is a quorum of an ethics committee meeting (EC), however, the EC meeting should be adjourned still the absentee of a layperson (WHO 2011). So layperson is a very important position in the EC. Nonetheless, the term "layman" makes their role in IRB meeting less valuable.

Actually, the responsibility of the non-scientific members in the research area ensure the overall public's representation that the individual's views are adequately safeguarded by the research participants (Robinson, 1991). Non-scientists IRB members are often described as "public members," "community members," and "public" or "community representatives" (Hayes 1995). Other non-scientific members are much valued; they are considered as public representatives rather than the layperson

in culturally specific. The term lay person may have a negative connotation in scientific research endeavors. Therefore, my supposition is to change the nomenclature "layma n" to "public or patient representative".

If we recall the change of nomenclature of research subject to research participants, where, research "subject" is the more traditional form. The change of nomenclature of research "subject" to use research "participant" required over the past 25 years with many arguments when referring to individuals who take part in research, the term participants is more respectful than research subject (Deng 2020, The New England Journal of Medicine, American Journal of Public Health, and Internatio na l Committee of Medical Journal Editors all use the term participant in the publicat io n exclusively. NIH Director Francis Collins is quoted as saying, "Medical advances would not be possible without participants in clinical trials suggesting that the word "subject" should be banned from reports of research on humans. The word "subject" is demeaning (Bromley et al 2015**).**

Social scientists have emphasized that word choice influences the researchers thinking on study participants and the respect that they have for them (Agboka, Godwin Y. 2020). Thus, it is important to find out the evidence for giving emphasis to change the term and transform this term as valued one. Moreover, evidence-based research showed that 92 percent of laypersons had at least a bachelor's degree remaining had an advanced degree including Ph.D (Robert et al 2008). So they have some knowledge on science and research.

The aim of this study is to provide justification the needs of changing the term of "lay man "in the research endeavour. For this reason, there is an understanding of patients as well as the public must be engaged in the debate.

METHODOLOGY

The research was done between January to March 2023 based on a literature review. Pubmed, Google Scholar, Embase, Hinary, online library, and Web of Science were the possible search engine for literature. The article published in English was reviewed only. Keywords for search articles were layperson, public representative, IRB, and

nomenclature. Primary sources were books, journals, and articles plus other published literature and academic treatises. Secondary sources were official documents, speeches, and websites plus other online sources.

The article was organized into six sections. The first and second contained an introduction and methodology respectively. Regarding layperson in EC was organized in section 3. Discussion and Conclusion were planned in section 4 and 5. Finally, references in section 6.

LAYPERSON

Lay or layman origins from the Greek worlds laikos, which means of the people (Wikipedia 2023). Lay is an adjective that means relating to the general people. Sometimes layman is also referred to as a lay member or layperson. In the case of gender-specific, it is also called lay woman. Layperson comes from the term laity, which means non-professional. In a Christia n religious denomination, the laity means those who are not part of the clergy but come from general people e.g. a nun or a lay brother. Traditionally, lay appointed by individual churches to continue preaching to local people and invite them to nearby churches. So, a layperson is an individual who belongs to a religious group but is neither compensated nor otherwise qualified in a particular field (Cambridge Dictionary, 2023). Laymen also play important roles in Jews, Christians, and Buddhists (Wikipedia 2023). However, in the judiciary system, the use of common, unskilled persons is referred to as using "lay people" for engaging regular citizens in courts to make the system better and prevent criticism of the judiciar y for deciding in private (Law teacher, 2019).

In scientific literature, a layperson is a person who is 'not practicing or trained in any medical or paramedical discipline' First and foremost responsibility of a layman is to ensure the interests of the patient, or participants of the research (Robinson 1991). The Code of Federal Regulations 45 Part 46 states that each IRB includes at least one scientific member, one non-affiliated member with the institution, and one non-scientific member. If only one non-scientific member in the IRB, it should be the layperson (U.S. Department of Health and Human Services 1983). Therefore, it is

understandable how the importance of the role and responsibility of the layperson in the IRB.

Importance of Layperson in Ethics Committee: The impact of laypeople' s roles and responsibilities on the work of ethical committees in clinical studies involvi ng human beings should need to be understood. The layperson review the informed consent form the patient's perspective to safeguard the participant from harm. To safeguard the research participants of course equally the duty of the medical members, but it is the presence of lay members on the committee that is intended to reassure public opinion that the participant's interests are fully protected. However, there is a general public misconception, that doctors will always support one another in the pursuit of medical research without fully taking into account the hazards or the pain or discomfort suffered by the participants (Robinson 1991). For this reason, the inclusion of general people in the IRB ensures the patients are safeguarded adequately (Robinson, 1991). It is acknowledged that engaging layman in research in an important way instead of in an insignificant one can be vital and challenging (Snape et al., 2014).

DISCUSSION

Why the nomenclature of layperson needs to be changed?

The advantages of public engagement in research on social and health care are becoming more popular. Yet, there hasn't been much evidence on the general people's involvement values directly or how they might vary for various groups in the study' s procedure (Snape et al., 2014b). One research conducted in UK demonstrated how deeply public involvement is ingrained in research. They also draw attention to the requirement for "the most effective practice" guidelines to help research teams to assess general people's participation (Barber et al., 2011). These results were utilized in the creation of the public involvement impact assessment framework (PiiAF), which provides direction to researchers and members of the public engaged in the research area (Snape et al., 2014). Greenhalgh et al. (2019) state that patients and the public named as the layman commonly value subjects for study that are separate from those of academics and healthcare professionals. The layman who has a medical condition is

frequently in a better position to determine what study would probably improve the standard of life and what questions still need to be answered regarding the medical care or condition of participants (Evans and Brown, 2016). The most important and relevant measurements of outcome in clinical trials are frequently discussed with the general people or the layman (Initiative 2016). Layman's participation by the public may influence which research results are assessed as well as the way they are determined, making the results of the study more useful and important for those who want to use them (Hogg and Williamson, 2001). Therefore, the role and function of the layman is very important in the IRB. Nevertheless, according to my 20 years of experience, the term "laypersons" were considered a little less valuable position than other non-scientific members in an IRB meeting, of course, it may be culturally specific. Though the term "layman" is not literally offensive, however, just because it sounds funny when their educational status is as high as PhD. We never say the general people as "the layman," which may seem to be third person and sounds unusual. It is derogatory or offensive connotations. Further, we never say any person has less expertise than others and he is the layman, it may offend them. Should we retain in our old traditions? This is the almost end of the 1 st quarter of 21 century. We are educated society should reflect our intellect. IRB has good community members, we may not use the term "layman" as a substitute for "general public" or "ordinary folk", and yes it could be construed as a bit offensive. If we do It will almost on the part of our paupers (Klitzman 2021).

Most frequently, the word "layman" is used to compare with "expert" or "professional". If people don't use it to expressly refer to professionals, it could be disrespectful to a "self-proclaimed" specialist who lacks the necessary knowledge or as a general statement (Lumberjack 2015). The layman" may be seen as suspect of less knowledgeable in our elevated sense of education. The term layperson may have a negative connotation for me, conjuring up the image of cold scientific research. When a word is made the person less valuable then that word should be unacceptable.

There are many examples of change of nomenclature for showing better respect to the profession. For example, the term "research subject". The change of term from "subject" to "participant" has caused much controversy over the past 25 years regarding those involved in research. Awareness of the modern scientific community is higher

than that of traditionalists (Deng 2020). The Director of the National Institutes of Health (NIH) Dr Francis Collins stated, "It is derogatory to use the word "subject" for research "participants" as the medical advancement is not possible without research participants. This word "subject" should be eliminated for the reporting of human investigatio ns. (Bromley et al. 2015). Therefore, the term "participants" are exclusively referred to the research and publications.

Another example of the change of term is "pharmaceutical salesman". Pharmaceutical sales typically entail working for a pharmaceutical company that sells information of medication to hospitals and physicians. The "team pharmaceutica l salesman" over time has been changed to a "medical representative". A medical representative has a positive connotation and is respectful as well as accepted by all.

In some IRB the layperson is expected to view the protocol dispassionate l y. They only look for compensation in the informed consent form. If training for laypersons should be provided so the laypersons may have to ability to voice their views and discuss ethical aspects among scientific expert members comfortably. They can also discuss the risk-benefit, cultural, and social perspectives in the informed consent process and questionnaire or protocol.

CONCLUSION

In response to my argument, I point out that there are examples of changes of terminology e.g. "subject" to "participant", and "pharmaceutical salesman" to "medica l representative". Like the above examples the term "layperson" to "public representative" should be changed to value their important role and responsibilities in the IRB. Once there are laws/guidelines that are in place but deem unacceptable and over time should subsequently modify. Therefore, it is high time to change the term "layman" to "public representative". General and special training should be provided to public representatives so that they can provide their insight into the risk-benefit, cultural, and social perspectives of the informed consent process and questionnaire from public/patient perspectives efficiently. Then the value of layman will be the same as other no-scientific members in the IRB.

REFERENCES

Barber, R., Boote, J.D., Parry, G.D., Cooper, C.L., Yeeles, P. and Cook, S. (2011). Can the impact of public involvement on research be evaluated? A mixed methods study. Health Expectations, 15(3), pp.229–241. doi: https://doi.org/10.1111/j.1369-7625.2010.00660.x.

Bromley, E., Mikesell, L., Jones, F., & Khodyakov, D. (2015). From subject to participant: ethics and the evolving role of community in health research. *American journal of public health*, *105*(5), 900–908. https://doi.org/10.2105/AJPH.2014.302403

Cambridge Dictionary (2023). Layman. [online] *CambridgeWords*. Available at: https://dictionary.cambridge.org/dictionary/english/layman (Accessed on Jan 2023)

Deng. (2020). Participants, Patients, Subjects, Volunteers, What to Use?) . *On Biostatistics and Clinical Trials (Online).* http://onbiostatistics.blogspot.com/2020/08/participants-patients-subjects.html (Accessed on Feb 2023).

Evans, N.J. & Brown, S.D. (2016). People adopt optimal policies in simple decision - making, after practice and guidance. Psychonomic Bulletin & Review, 24(2), pp.597–606. DOI: https://doi.org/10.3758/s13423-016-1135-1.

Law. Teacher (2021). Lay People and Their Role as Magistrates and Jurors. [online] *Lawteacher.net*. https://www.lawteacher.net/free-law-essays/common-law/the-term-lay-people.php?vref=1 (Accessed on Feb 2023)

Lumberjack, J. (2015). Is 'layman' an offensive term? [online] English Language & Usage Stack Exchange. Available at: https://english.stackexchange.com/questions/224241/is- layman-an-offensive-term (Accessed 22 Apr. 2023).

Garfield, S., Jheeta, S., Husson, F., Jacklin, A., Bischler, A., Norton, C. and Franklin, B.D. (2016). Lay involvement in the analysis of qualitative data in health services research: a descriptive study. Research Involvement and Engageme nt, 2(1). DOI: https://doi.org/10.1186/s40900-016-0041-z.

Greenhalgh, T., Hinton, L., Finlay, T., Macfarlane, A., Fahy, N., Clyde, B. & Chant, A. (2019). Frameworks for supporting patient and public involvement in research: Systematic review and co- design pilot. Health Expectations, 22(4), pp.785–801. DOI: https://doi.org/10.1111/hex.12888.

Hogg, C., & Williamson, C. (2001). Whose interests do lay people represent? Towards an understanding of the role of lay people as members of committees. *Health Expectations*, 4(1), pp.2–9. DOI: https://doi.org/10.1046/j.1369-6513.2001.00106.x.

Hayes, G. J., Hayes, S. C., & Dykstra, T. (1995). A survey of university institutio na l review boards: characteristics, policies, and procedures. *IRB*, *17*(3), 1–6.

initiative, C. (2016). COMET Initiative | Home. [online] www.comet-initiative.org . Available at: https://www.comet-initiative.org/ [Accessed 22 Apr. 2023].

Gremillion, H., Tolich, M., & Bathurst, R. (2015). Lay members of New Zealand research ethics committees: Who and what do they represent. *Research Ethics*, Vol. 11(2) 82–97. DOI: https://doi.org//10.1177/1747016115581723

Klitzman R. (2012). Institutional review board community members: who are they, what do they do, and whom do they represent? *Academic medicine : journal of*

the Association of American Medical Colleges, *87*(7), 975–981. DOI: https://doi.org/10.1097/ACM.0b013e3182578b54

Kaye, D.K. Lay persons' perception of the requirements for research in emergency obstetric and newborn care. *BMC Med Ethics* **22**, 1 (2021). https://doi.org/10.1186/s12910-020-00568-1

Robinson, K. (1991). The layman's role in a research ethics committee. Journal of the Royal College of Physicians of London, [online] 25(1), p.43. https://pubmed.ncbi.nlm.nih.gov/2023154/ [Accessed 22 Apr. 2023].

Robert, D. Allison, Lura J. A., & Wichman, A. (2008). Roles and Experiences of Non-scientist Institutional Review Board Members at the National Institutes of Health. *IRB.* 2008 ; 30(5): 8–13.

Snape, D., Kirkham, J., Britten, N., Froggatt, K., Gradinger, F., Lobban, F., Popay, J., Wyatt, K. and Jacoby, A. (2014a). Exploring perceived barriers, drivers, impacts and the need for evaluation of public involvement in health and social care research: a modified Delphi study. *BMJ Open*, 4(6), pp.e004943–e004943. doi: https://doi.org/10.1136/bmjopen-2014-004943.

Snape, D., Kirkham, J., Preston, J., Popay, J., Britten, N., Collins, M., Froggatt, K., Gibson, A., Lobban, F., Wyatt, K. and Jacoby, A. (2014b). Exploring areas of consensus and conflict around values underpinning public involvement in health and social care research: a modified Delphi study. *BMJ Open*, 4(1), p.e004217. Doi: https://doi.org/10.1136/bmjopen-2013-004217.

Tripathi, S.K. (2012). Who is Lay Person as per the EC requirement of Schedule Y? *Researchgate.com* (online) https://www.researchgate.net/post/Who-is-Lay-Person- (Accessed on April 2023)

U.S. Department of Health and Human Services, Public Health Servics. (1983). OPRR Reports, Code of Federal Regulations 45CFR46 and Certain other Related Laws and Regulations in Protection of Human Subjects. *National Institutes of Health.* Bethesda.

WHO.(2011). Standard and Operation guidelines for Ethics Review Health Related Research with Human Participation. Geneva.

Wikipedia. (2023). Laity. (Online). https://en.wikipedia.org/wiki/Laity (Accessed on Jan 2023).