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Case Report

A Critical Examination of Research Ethics in Treatment Recommendations for Diarrhoea

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Abstract: This case study emphasises that when conducting research, especially one involving human subjects, researchers are expected to comply with applicable global and national ethical standards. If a researcher fails to do so, he/she stands the risk of breaching research ethics, and this is capable of rendering his/her research unacceptable. Accordingly, this article, making reference to relevant ethical theories, critically examines and analyses the actions of a researcher who set out to investigate treatment recommendations for diarrhoea. Ultimately, a number of ethical pitfalls in the stated case report are x-rayed. This article also aims to evaluate the actions of the researcher, with reference to ethical principles, such as deontologism, utilitarianism, Immanuel Kant's Humanity Principle, and Common Good. Finally, some recommendations for the study are provided in this paper as well.

Keywords: Research ethics, diarrhoea, diarrhoea research, informed consent, pharmacists, IRB, educational intervention

Introduction: Globally, research, especially when it involves the participation of human subjects, ought to be conducted in accordance with laid-down ethical principles. Two of such principles, for instance, are respect for persons[1] and recognition of the right of individuals (research participants)[2]. These principles, in accordance with contemporary norms of research ethics and the World Medical Association's Declaration of Helsinki[3], basically demand that when conducting researches involving human subjects, researchers should endeavour to respect the rights of research participants[4]. When a

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researcher fails to do this, the ultimate result is the violation of research standards, which may inadvertently result in the unacceptability of such research. Thus, for research to be acceptable and implementable, it should not contravene research ethics in any way. The quest of this article is to critically examine and analyse the case of a researcher who sets out to investigate treatment recommendations relating to diarrhoea. Around 5 million children under 5-9 years die of diarrhoea each year[5]. In fact, diarrhoea is the third topmost cause of death of under 5 years children in low and middle-income countries[5]. According to a study in Bangladesh, diarrhoea is defined as the passage of three or more loose or liquid stools per day in children[6,7]. The main causes of death of diarrhoea are severe dehydration and fluid loss[5]. The disease burden is highest in African regions across all age groups, with an estimated 1.008 billion diarrhoea cases and 515,031 diarrhoea deaths in 2020[8]. Therefore, researchers undertook an in-depth review and critical analysis of a real-world case where an investigator at an infectious disease hospital in a South Asian country conducted a study to understand the treatment recommendations provided by drug sellers and pharmacists for diarrhoea. This article identifies some ethical issues arising from the diarrhoeal research under consideration, namely: deception, failure to consult an Ethics Committee or Institutional Review Board (IRB), infringement of privacy, lack of informed consent, lack of voluntary participation, exploitation, and breach of global research ethics codes and regulations. In other words, Precisely, the aim here is to evaluate the actions of the researcher, with particular reference to applicable ethical principles, such as deontology[6,9], utilitarianism[10], Immanuel Kant's Humanity Principle, and Common Good[11]. Finally, this article recommends some alternative approaches to the above case on diarrhoea investigation.

Methodology: This case study, which was conducted between January and March 2024, involves an in-depth review and critical analysis of a case where a researcher set out to investigate treatment recommendations provided by drug sellers and pharmacists for diarrhoea. The paper, drawing insights from major ethical theories and frameworks, such as Utilitarianism, Kant's Humanity Principle, and Common Good, evaluates the investigator's actions. PubMed, Embass, Google Scholar, CINAHL, and other institutional repositories were the search engines used for this research. The researchers searched databases by using the following keywords: research ethics, diarrhoea, informed consent, pharmacists, Institutional Review Board (IRB), and educational intervention.

Case Report of Treatment Recommendations for Diarrhoea: The case under contention here is simply one involving an ethical dilemma in a study proposed by an investigator at an infectious disease hospital in a South Asian country. The investigator wishes to explore what remedies drug sellers and pharmacists are recommending for diarrhoea treatment, with the long-term goal of creating educational materials to inform both drug sellers and patients. The investigator believes that the drug sellers and pharmacists would not provide truthful answers if they knew they were part of a research study. Therefore, he proposes a study in which four young men, disguised as villagers, will visit drug sellers and pharmacists, claiming to have a two-year-old child with diarrhoea and fever. They will request advice and purchase the recommended drugs. The survey would last one week, and each "villager" would visit up to six shops. The drug sellers would not be informed of the actual research purpose, and their shops would remain anonymous in the final report. The study aims to catalogue the recommended treatments and evaluate whether any of the suggested remedies poses risks to patients. If dangerous remedies are identified, the investigator plans to conduct educational interventions with those specific drug sellers[12].

Obviously, the methodology adopted in the above case involves deception, and this raises serious ethical questions, particularly regarding the ethical principle of informed consent. Recall that the entire study would take place without the drug sellers' knowledge or consent, which raises key ethical concerns

related to the bioethical principles of non-maleficence and justice.

Some Questions Arising from the Above Case Report of Treatment Recommendations for Diarrhoea:

1. **(**I) Do the drug sellers have a right to know that they were participants in a research study?
   (II) Was this right violated by the study, and
   (III) Would the study be unethical because of this violation?
2. (I) Did this study place customers at risk?
   (II) What were the risks to the drug sellers?
   (III) What were the potential benefits for the community?
   (IV) Did the prospect of these benefits justify these risks?
3. (I) Should the investigator have returned to debrief all the drug sellers (tell them the truth about the visits) after the week-long shopping survey was completed?

Discussion: The drug sellers have a right to know that they are participants in a research/study. Since this right was violated by the investigator, the study is inherently unethical. The affirmative answer given here is necessitated by research ethics, which is "...the application of fundamental ethical principles to research activities which include the design and implementation of research, respect towards society and others, the use of resources and research outputs, scientific misconduct and the regulation of research"[14]. In other words, by research ethics, we refer to a collection or set of principles, codes or standards guiding or regulating research activities globally. The case under review here clearly contravenes research ethics because the participants were not informed about the study, neither did they consent to it. Knowing one's status as a participant in a research/study is one of the global ethical principles guiding researches involving human subjects.

The right to be aware of one's status as a participant in research is clearly buttressed by the ethical principles of "informed consent," which is implicit in the Nuremberg Code of 1948[15], and "respect for persons," which is deducible from the Belmont Report of 1979[16], following the Tuskegee Study of 1932-1972.[17] Thus, the drug sellers should have been made to know beforehand that they would be participating in research. This would have given them the opportunity to either agree or disagree to be involved in the research.

Since the study involved non-consenting participants, the conclusion necessarily follows that the behaviour of the investigator is unethical. Precisely, unethical behaviour refers to actions that cause harm to others through "either illegal or marginally unacceptable conduct"[13]. Moreover, teleologism, one of the consequentialist ethical theories, considers a behaviour ethical or unethical based on the resulting benefits or risks of that behaviour[18]. Although the deontological method, grounded in predetermined guidelines, emphasises the correctness of the process rather than the outcome[6,9], ethical researches should always adhere to principles found in the Nuremberg Code, the Belmont Report, the Declaration of Helsinki, and CIOMS, all of which reflect Immanuel Kant's (1724-1804) deontological theory, which stresses duty-bound obligations researchers must follow[9].

One of the major theses of the ethical theory of utilitarianism, as advocated by scholars such as Jeremy Bentham (1748-1832) and John Stuart Mill (1806-1873), is the principle of "the greatest good for the greatest number." According to these scholars, an action is morally right if it ensures or brings about the happiness of the larger society[10]. In other words, an action, decision, or idea is considered morally permissible if it serves the common good or benefits the greatest number of people. In many developing countries, including countries in South Asia, medicines for the treatment of diarrhoea are often purchased from pharmacies without a doctor's prescription. A cross-sectional study from Pakistan showed that the management of paediatric diarrhoea and diarrhoeal diagnostic testing by drug sellers—without doctors' supervision—may pose a risk to the community. However, in low-resource settings,

dispensing drugs without prescriptions may serve the greater good by saving lives. Consequently, the World Health Organisation (WHO) aims to improve the quality of drug sellers in such settings[20].

Concerning the study under contention here, we can argue that the researcher was wise to plan to intervene with any drug seller whose recommendations place customers at risk, any risk, or great risk, as doing so will prevent many persons from harm, thereby leading to happiness of the larger society. Again, using the ethical principle of "common good," which is also deducible from the view of the utilitarianists[21] as a basis, we can infer that the investigator is ethically obligated to intervene with any seller whose recommendations are harmful to people. Since the investigator has acquired this special knowledge through his study, he must act accordingly to save humanity from further harm. If the investigator fails to do so, he will be contravening the ethical principles of utilitarianism and the common good.

Yet, no doubt, the prospect of the above-stated benefits gives some justification to the risks identified above. However, this is merely a partial justification, as the study itself was conducted deceitfully. Deceit is considered a sin in some cultures. In the context of surrogacy or adoption, hiding information about a child's genetic lineage is viewed as deceit, as these cultures believe that individuals have the right to know their full parentage[22]. Owing to deceit, the investigator in the above case report of treatment recommendations for diarrhoea can be said to have breached a famous moral dictum; the Humanity Principle of Immanuel Kant "...never treat humanity as a means to an end, but as an end in itself"[11]. This principle can also be formulated as follows: "so act as to treat humanity, whether in thine own person or in that of any other, in every case as an end withal, never as a means only"[23]. By this principle, Kant seeks to promote respect for the dignity of the human person and ensure that the human person is not objectified or exploited; that is, treated, not as a means to an end, but as an end in him/herself. The researcher in this study fails to uphold this principle. By failing to conduct the research openly, the researcher can therefore be said to be guilty of exploiting and objectifying the non-consenting research participants. Even though the findings of the researcher are useful to the society, we still cannot totally exonerate him from blame, as he is certainly guilty of breaching research ethics.

So, the investigator should have returned to debrief all the proprietors (tell them the truth about the visits) after the week-long shopping survey was completed. Even though this would not totally exonerate him from ethical culpability, it would have served the purpose of getting some level of post-study consent from the participants.

Recommendations of Alternative Approaches to the Above Case Report on Diarrhoea Treatment: The investigator could have considered alternative research methods that do not involve deception or that minimise the ethical issues associated with deception. For instance:

(a) Surveys or Interviews: The investigator could develop anonymous surveys or structured interviews with drug sellers, clearly explaining the purpose of the study and obtaining their consent. This would allow drug sellers to participate voluntarily and provide honest responses, possibly with assurances that their identities and responses would remain confidential.

(b) Educational Workshops: Instead of a covert study, the investigator could conduct educational workshops with drug sellers, offering training on appropriate treatments for diarrhoea and using the workshops as an opportunity to gather data on current practices.

(c) Community Engagement: Engaging local communities, including drug sellers, in a dialogue about healthcare practices and the importance of appropriate drug use for diarrheal diseases could lead to better outcomes without the need for

deception. Collaborative research could build trust and lead to more sustainable improvements in healthcare practices.

Conclusion: In any research project involving human subjects, compliance with both global and national ethical standards is not just recommended, but required. This is particularly true for studies like the one described above, which seek to investigate treatment recommendations for diarrhoea. The case in question highlights an ethical dilemma where deception is employed, raising concerns about the violation of key ethical principles, including informed consent, non-maleficence, and justice. The absence of informed consent in the proposed methodology, along with the deceptive nature of the study, threatens the ethical integrity of the research and undermines the trust between researchers and participants. Additionally, failing to notify an Ethics Committee or Institutional Review Board (IRB) disregards the established processes for ethical oversight that are designed to protect human subjects.

While the investigator's goal of improving public health is commendable, the methodology involving deception and the lack of participant consent cannot be ethically justified without significant modifications. Thus, the study demonstrates a clear need for ethical rigor, particularly in the areas of transparency and the treatment of participants.

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