Chapter

Ethical Considerations for Health Research Data Governance

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Abstract

Research involving humans often generates considerable data irrespective of the context in which the research is being conducted. This data must be protected from unauthorized access, use, and sharing as a means of safe-guarding research participants' rights. Notwithstanding the fact that several jurisdictions globally have promulgated laws and regulations aimed at protecting individual citizens' personal information, violation of privacy and related rights occurs in some instances. This could partly relate to a general lack of health research sector specific data governance policies and laws, which include data transfer agreements prevalent in most countries. The chapter therefore aims to cover the ethical aspects of health research data access, use, and sharing as a means of enabling health research institutions and policymakers to develop robust data governance structures and procedures. The scope of the chapter covers health research data generated in empirical research as well as that which is produced within a medical laboratory research context, i.e., human sample associated data.

Keywords: data access, data use, data sharing, data governance, privacy, confidentiality

1. Introduction

Data governance is defined as "all processes related to the collection, storage, processing, curation, use, and deletion of data" [1]. Data governance entails not only the development and rules for data quality management but also specifying the responsibility for making decisions related to data handling as well as the duties related to such decisions [2]. Data governance also assures compliance with the laws governing data [3]. Notably, there is a presumption that data governance is a universal approach with a one size that fits all organizations alike. Weber et al. argue that this should not be the case [3]. Accordingly, data governance within the health research context is considered in this chapter. In the context of this chapter, health research data governance refers to the development of structures and processes for the access, use, and sharing of health research data. The question of why data governance matters in the context of health research is that it is mainly for the purpose of safe-guarding the individual data subject's rights by the data custodians. Infamous cases of unauthorized health research data access, use, and sharing have been well documented [4, 5]. This is despite the existence of regulations aimed at protecting individual citizens' personal information in certain countries. To demonstrate the issue of health research data use

that is not in line with consent granted, health research data misuse is discussed in this chapter. A key consideration for using personal information in medical research is to seek informed consent [6]. Accordingly, health research data and consent will be discussed in this chapter.

2. Governance of health research data

According to the WMA Declaration of Taipei, governance of health databases should be based on the principles of [7]: (1) protection of individual rights' over the interests of other stakeholders of science; (2) transparency in making any relevant information available to the public; (3) participation and inclusion of individuals and communities by health database custodians through consultations and engagement as well as (4) accountability in that custodians of health databases should be accessible to all stakeholders. Correspondingly, each of these principles for data governance is discussed in turn in subsequent sections.

The individual (human participant) rights to data (interchangeably health research data herein) access that should be respected include the right to privacy and confidentiality, notably, anonymization or confidentiality measures for ensuring confidentiality should be considered by the data custodians [8]. Other applicable rights that ought to be observed with respect to data access, use, and sharing include the right to autonomy and the right to dignity [7]. Human rights should be protected by the rule of law [9] and as such human rights are inalienable (should not be taken away) except in specific circumstances, e.g., restriction of liberty if a person is found guilty of committing a crime by a court of law [10]. The CIOMS ethical guidelines also recommend governance systems that uphold the principle of accountability while maintaining good stewardship for samples and their associated data [11].

Some of the elements for governance of health data (including health research data) include, *inter alia*: arrangements for duration of data storage; nature and purpose of data collection; arrangements for disposal and destruction of data; arrangement for dealing with the data in the event of change of ownership, obtaining consent, protecting the rights of data subjects (interchangeably research participants herein); criteria and procedures for data access and sharing as well as measures to prevent unauthorized access or inappropriate sharing as well as; responsibility for data governance [7].

2.1 Protection of data subjects' rights

As already mentioned, the rights that must be protected in relation to access, use, and sharing of personal information are the rights to: privacy and confidentiality; autonomy and dignity.

Confidential information is that which is sensitive, needs protection, and can only be disclosed in a trusting relationship [12]. A recommendation for maintaining confidentiality of health research data is through anonymization or coding in order to protect the participant (data subject) from harm or stigmatization [11]. Moreover, confidentiality is a significant standard of professionalism [12]. Privacy on the other hand is difficult to define, with no universally accepted definition and has been subject to extensive debate by philosophers and legal scholars [13]. In modern society, however, the term addresses the question of who has access to personal information and the conditions of such access [13]. Primary justification for protecting privacy of

persons is to protect their interests [13]. Based on this notion, it follows then that ethical justification for protecting privacy of persons aligns with the notion of respecting participant's autonomy (self-determination) by virtue of the objective of privacy being to protect individual interests.

Professional codes of practice for healthcare professionals sometimes appeal to norms of respecting autonomy and privacy as well as not harming others (non-maleficence) although these norms are not explicitly expressed in such codes [14]. The rights to autonomy, privacy, and confidentiality call for not only protection of bodily integrity, but also that the scope of decision-making should be free from interference by others [15]. It can therefore be inferred that access and use of health research data that are outside the scope of the data subject's decision-making for participation (consent) violate these rights. Some of the factors that promote noncompliance of the principles of ethics in health research include lack of ethical supervision; paternalism caused by trust in the researcher, resulting in a subtle loss of participant autonomy; informed consent documents that do not adequately address all aspects of research participation, in particular the potential risks involved, thereby threatening autonomy and engendering maleficence if there are any risks involved; lack of legislation to protect participants and pressure for researchers to increase research output at the expense of ethical principles [16].

2.2 Transparency in data governance

Smits and Champagne define transparency as the disclosure of procedure and results [17]. Mahsa and Mojisola consider transparency to be "the development and public availability of data sharing and access policies" [18]. Notably, there is no single conception of transparency, but rather it has multiple definitions, purposes, and applications with users of transparency including self-governing citizens, governments, and private firms [19]. Transparent governance for health data requires clear information for data circulation, data-sharing agreements, research objectives, and findings to be made available to the public [20]. In the context of biobank governance, transparency enables donors to better understand biobank governance and thereby make better, more informed decisions about sample and associated data donation as well as research participation [21]. Lack of transparency has the potential to undermine public trust in initiatives that involve large datasets such as biobanks [21].

A notable limitation of making information available to the public is that of web based transparency particularly for communities that lack web access or information technology infrastructure [21]. If data collection or use raises specific ethical questions, e.g., with regard to consent and transparency as well as privacy and data subjects' rights and expectations, an explanation of how the ethical concerns will be mitigated is requisite in the operational plan for data collection and processing [22]. Community engagement has been identified as an important element of ethical research data sharing by research stakeholders that include researchers and health providers, community representatives, assistant chiefs, and field workers [23].

2.3 Community and individual engagement in the context of health research data governance

Community (public) engagement is perceived as a means of cultivating public trust and cooperation in research activities [24]. Ethical justification for community

engagement is that it improves the consent process, identifies ethical issues and develops processes for resolving ethical issues when they arise [25]. Jao et al. identified a number of community engagement goals in relation to health research data access, and these include: (1) creating an awareness of data sharing activities with information on how any benefits and risks would be managed; (2) giving feedback to the community or representatives on the data sharing process; (3) ad hoc community consultation in relation to specific data sharing requests [23]. Evans et al. propose Community Advisory Boards (CABs) as platforms to engage the affected populations on how they would want their data to be collected, stored, and shared [26]. The Mayo Clinic Biobank CABs provide a way of incorporating interested community groups in the governance of large-scale bio-resources [27].

Engagement of research participant groups as well is important because: participants are in a better position to speak to the risks associated with the use of their data as well as having an interest in the use of their data, which the public might not necessarily have [27]. Moreover, engaging participants in data management decisions has been cited as strengthening transparency and accountability [28].

2.4 Accountability for health research data

The WMA defines accountability as that which "requires being prepared to provide an explanation for something one has done or has not done" [7]. Accountability represents a moral obligation to answer and the practical ability to convey that answer [29]. Moreover, accountability serves to establish responsibilities [29]. In the context of health research data governance, it is the responsibilities of the data custodians that should be established. This chapter refers to data custodianship rather than ownership because firstly, claiming ownership rights of data is a misconception in that proprietary rights over data do not exist in the international intellectual property (IP) system [30]. Secondly, because trends on claims of data ownership are based on "flawed models and on implausible arguments" [30]. Data custodians are also referred to as stewards [31]. Accordingly, data steward(ship) and custodian(ship) will be used interchangeably in this chapter. The concept of a data steward is intended to denote a level of fiduciary (trust) responsibility toward the data [32]. Moreover, responsibilities for data stewardship are conceptualized and fulfilled by the process of governance [32]. Data stewardship entails the existence of mechanisms for the responsible acquisition, storage, safe-guarding, and use of data [32]. The concept of custodians should also ensure the existence of systems that ensure privacy of individuals at every stage [33] as well as ensuring an adequate level of confidentiality of such data in order to preserve the data as much as possible for the researchers [8].

Empirical research conducted in Australian data custodians shows that they perceive their role to be more of protecting data subjects' privacy than other vulnerabilities [31]. Data custodians also have the responsibility of ensuring that data sharing complies with legal and policy requirements prior authorizing the release of data on behalf of institutions [31].

3. Ethical considerations and issues in health research data access, sharing, and use

There is a wide recognition that sharing of data generated from research involving humans raises ethical and governance issues [34]. Some of the issues (risks) of

data access and sharing include: (1) confidentiality and privacy breaches as well as the need to manage these two aspects and (2) violation of expectations of data reuse [35]. These are ethical challenges because of their potential to violate human dignity and autonomy as well as pose a risk of discrimination [35]. Other ethical considerations for data sharing include: valid consent particularly when future uses of data are unclear; the potential impact of such sharing on public trust and implication for future research in terms of inappropriate data use, e.g., publication of data in discriminatory ways and issues related to decisions on data access [36]. According to interviewees in a study on health research data ethical practices conducted in South Africa (SA), researchers have an ethical duty to provide accurate data as a means of nurturing professional integrity through transparent practice, coupled with avoidance of unauthorized future research use [37]. Such stakeholder views should be addressed by policies to ensure ethical data sharing nationally and internationally [37]. The noted ethical issues pertaining to health research data access, sharing, and use are discussed in turn in the subsequent sections.

3.1 Health research data breaches

Sharing of research data requires adequate safeguards for the protection of participants' rights and should also be fully consistent with the terms of consent granted [38]. Unauthorized users are able to access databases due to vulnerabilities in software, human error, and security failures resulting in sensitive data being exposed leading to confidentiality breaches [39]. Lord et al. argue that using anonymized health research data need not be regarded as a confidentiality breach claiming that informed consent is unnecessary and often impractical [40]. The basis for this claim is unclear but seems to be based on the notion that anonymized data use benefits outweigh any confidentiality issues. Anonymization is the process of irreversibly removing from a dataset those variables that can identify an individual [41]. In the context of this chapter, health research data misuse refers to access, sharing, and use of such data that is not in line with consent granted. There is paucity of literature on misuse of health research data; however, a case in point is that of an alleged report of African sample associated data that was transferred from SA to the UK to develop gene chips [5]. Neither SA researchers nor research participants were aware of such purported commercialization of African health research data [5]. If proven to be true, such allegations demonstrate a violation of research participants' autonomy and dignity. When data are not anonymized, the risk of malevolent exploitation seems to be significantly increased [42].

Iceland Health Sector Database (HSD) legislation and the visibility of its processes have exposed the innovation of genomics to a public debate resulting in exposure of ethical issues of commodification of bioinformatics (the fusion of biotechnology and informatics) and human tissue to the international cultural and political agenda [43]. Nicolson argues that data reuse by healthcare professionals and researchers commodifies people's medical records and reduces such data to a commodity that can be bought and sold based on the reasoning that data reuse may reinforce social inequalities [44]. This argument does not hold, particularly when data reuse is in line with ethico-legal requirements.

Public forum comprising of respondents from professions in legal, ethics, medicine, medical, and social scientists, government professional, security, digital health, and bioinformatics in a study by Staunton et al. in 2019 in SA had a general awareness of the need for protection of personal health information [45].

3.2 Health research data reuse and consent

It is ethically mandatory for the data subject's rights to be protected [46]. Meystre et al. propose principles for ethical data reuse, and these include principles of: information (privacy and disposition—right to privacy and control the use of one's data); openness (appropriate and timely data disclosure); security (data protection through appropriate measures); least intrusive alternative (any violation of privacy or individual's right or control his/her data may occur in a least intrusive manner with minimal interference of the person's rights and accountability (infringement of rights and control of an individual's data must be justified to the affected individual in a timely and appropriate manner) [46]. A significant number of research participants across empirical research studies prefer to be contacted and re-consented for the reuse of their data [47]. The majority of Quebec citizens in a study by Cumyn et al. expressed support for the reuse of health data provided that individuals are informed about such use and consent is sought [48]. Reusing health data without informed consent contravenes patients' expectations resulting in violation of the patients' perceived ownership rights [49]. Moreover, autonomy is a fundamental human right, which may be limited during public health emergencies, provided that such an interference is deemed necessary [49]. Key issues in the discussion about limits for the use of personal data in medical research relate to the scope and limitations of consent as a legal basis for such use [50]. Moreover, one of the principles for processing of personal data in the European Union (EU) regulatory framework is lawfulness, which mandates consent or another legitimate basis (laid down by the law) as requirements for such processing [50].

As already mentioned, another ethical concern is when future uses of data are unclear; accordingly, the potential impact of such sharing on public trust follows in the next section.

3.3 The potential impact of unclear purpose of health data sharing on public trust

There is a long-standing doctor-patient trust relationship through which the doctor (or researcher in this context) is bound by professional integrity to act in the best interests of their patients (or research participants in this context) [51]. Kerasidou submits that trust is important in biomedical research and that professional integrity can promote trust in research [52]. The presence of legally binding ethico-regulatory frameworks aimed at protecting the dignity of research participants enables the development of researcher-participant trust [53]. Trust is an essential element of building and maintaining mutual respect, particularly in relationships where there is an imbalance of power [54]. Kraft et al. have identified factors that influence research participants' trust, and these include: (1) participants' varying benefits expectations, (2) historical discrimination in research, (3) participants' fear that their data might be used inappropriately [55]. These factors will be explored in detail in subsequent sections. The latter factor aligns with health data breaches discussed in Section 3.1 and will therefore not be discussed further in this section. Trust issues in medical research are also caused by exploitation of vulnerable populations, different regulatory frameworks, particularly in research collaborations as well as lack of robust operational management particularly of biobanks as cited by SA researchers in a study conducted by Moodley et al. [56].

Trust relationship between researchers and participants is built when researchers share information, reciprocity based on integrity and equality in replacing

vulnerability and dependence [57]. It is not only prospective research information that can be shared with participants but also research findings through community (public) engagement as a means of building trust [58]. Public engagement has been identified as a key mechanism for building trust [59]. Another requirement for building the healthcare professional-patient trust relationship is confidentiality [60]. Therefore, trust imposes a duty of maintaining confidentiality on healthcare professionals.

3.3.1 Research participants' varying benefits expectations and trust

Molyneux et al. distinguish between direct benefits for research participants (e.g., diagnostic tests, distribution of medication, evaluation services) and indirect (collateral) benefits for those that are not specifically targeted at research participants but might include research participants as well (e.g., provision of healthcare services to family or community members) in a fair benefits framework [61]. A study conducted in Kenyan views and experiences on research participants' benefits and payments showed that inconsistencies in research benefits such as varying transport fares on different occasions for the same study has the potential for introducing participant mistrust [61]. Biobank research participants in a qualitative study in Australia declared institutional trust in that they did not necessarily trust the individual researchers but rather the research institution based on a perception that the institution carrying out the research was reputable [62]. Some researchers, particularly in the social and behavioral sciences, believe that research participant deception that does not involve any harm is justified, while those who oppose this view hold that such deception violates and takes advantage of participants' trust in scientists [63].

Benefit sharing in research, particularly in genetic data banking, is recommended not only from an ethical obligation point of view but also as a potential solution to resolving the issue of loss of public trust in a sense that benefit sharing is recognition for participants' contribution to the research endeavor [64]. Nicol and Critchley note that based on the notion of reprocity, biobanks, which reward contribution, through benefit sharing, should promote trust, which in turn leads to public participation in biomedical research [65]. Johnson et al., however, are of the opinion that patients are expected to participate in research without benefitting personally because research is a requirement for good-quality healthcare [66].

3.3.2 Historical discrimination in research

Literature on historical discrimination in research involving humans is dominated by the infamous Tuskegee study [67–69]. Briefly, the study that commenced in 1932 in the USA involving a total of 600 black men of which 399 had syphilis and 201 did not have the disease involved a number of ethical transgressions, which were inflicted on the research participants [70]. The ethical violations included participant consent not being sought as well as participants not being adequately informed in that they were misled on the purpose of sample collection under the guise that they were being treated for "bad blood" in exchange for free medical examinations, meals, and burial insurance. Another ethical transgression was the maleficence inflicted on the participants in that even when penicillin became widely available as a treatment of choice in 1943, the participants were not offered treatment [70]. By the time the study was terminated in 1972, after having being leaked by the press, out of the 399 participants who had syphilis, 28 had died, another 100 from syphilis-related complications, 40

patients' wives contracted the disease, and 19 children were infected at birth [71]. Lack of trust regarding the healthcare system and health researchers as cited by research participants, particularly African Americans, has historical roots, with the Tuskegee syphilis study having been cited either explicitly or implicitly and its impact continues throughout the generations [67]. Perceived discrimination contributes to higher societal distrust of African Americans in the healthcare system compared with their white counterparts [68]. Such historically nuanced concerns should be addressed by institutional review boards (IRBs) even though the process may be frustrating because such assessments are imprecise by nature [72]. An interesting finding by Brandon et al. revealed that black race, not necessarily knowledge about the Tuskegee study, was a predictor of medical care mistrust, and it is believed that African American mistrust arises from a general mistrust of societal institutions with the Tuskegee study being confirmation of what is speculated or already known about African American treatment in medical systems [69].

The Nuremberg trials involved specific crimes that took place during World War II in which German physicians conducted a series of more than 12 medical experiments in concentration camp inmates with some of the crimes involving killing of Jews for anatomical research, euthanasia of sick and disabled civilians, and killing of tubercular Poles [73].

4. Conclusion

This chapter has considered health research data governance through the lens of the WMA Declaration of Taipei that is based on requirements for: (1) protection of participants' rights; (2) transparency of information; (3) individual and community inclusion through engagement; and (4) accountability of health database custodians through being accessible to all stakeholders. The ethical considerations for health research data access, sharing, and use include: confidentiality and privacy breaches as well as the need to manage these two aspects; violations of expectations of data reuse; valid consent and the potential impact of such sharing on public trust. Factors that influence research participants' trust include: (1) varying benefits expectations, (2) historical discrimination in research, (3) participants' fear that their data might be used inappropriately. These factors have the potential to erode trust of health research data subjects because the context is the same, i.e., research.

Conflict of interest

The author declares no conflict of interest.

Acronyms and abbreviations

HSD	Iceland Health Sector Database
OECD	Organisation for Economic Co-operation and Development
SA	South Africa
WMA	World Medical Association

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