The Ethics Of Pharmacogenomic Testing In Community Pharmacy

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Abstract

Health care providers have traditionally provided individualized, patient-centered treatment plans to their patients; yet, the special significance that a patient's genetic profile plays in determining the success or failure of therapy has received little attention. Terms like precision medicine, personalized medicine, and pharmacogenomics (PGx) have generated discussion in the scientific and medical sectors due to recent improvements in the understanding and implementation of genetic-based care. Pharmacogenomics is the study of how an individual's genetic makeup affects how they react to pharmaceutical treatments. Applications of pharmacogenomics are numerous in clinical specializations and human health domains. This study is to investigate some of the most important ethical issues surrounding pharmacogenomic testing in community pharmacies as well as patient views regarding the practice.

Key Words: Ethics, Pharmacogenomic, Community, Pharmacy.

Introduction

Health care providers have traditionally provided individualized, patient-centered treatment plans to their patients; yet, the special significance that a patient's genetic profile plays in determining the success or failure of therapy has received little attention. Terms like precision medicine, personalized medicine, and pharmacogenomics (PGx) have become more popular in the scientific and medical sectors due to recent improvements in the understanding and implementation of genetic-based care [1].

While the study of how a patient's genetic makeup affects their health and the course of their medical care can be broadly characterized as these terms, PGx focuses on how a patient's genetic makeup affects their pharmacotherapy, with a particular emphasis on ensuring therapeutic efficacy and reducing unwanted effects. One cannot stress how crucial it is to use and interpret this information. The therapeutic Pharmacogenetics Implementation Consortium (CPIC) has published guidelines that explain how to interpret PGx tests and how to proceed with therapeutic care that is appropriate for each patient.3. Furthermore, the US Food and Drug Administration maintains a list of numerous drugs with pharmacogenetic connections [2].

While some hospitals have on-site PGx testing facilities, many do not, PGx testing may be particularly useful in the health system environment since results may be more instantly available and time-sensitive as new medications are initiated. Furthermore, the duration of the patient's stay may coincide with the testing turnaround time [3].

The study of pharmacogenomics focuses on how a person's genetic makeup affects how they react to pharmaceutical treatments. As demonstrated in, pharmacogenomics has wide applicability in several clinical disciplines and facets of human health.Pharmacogenomic testing has not been adopted in the clinical field at a consistent pace, despite the increased interest in genetics among the general public due to a number of factors, including direct-to-consumer testing, advancements in genetic engineering, mounting evidence of tThe importance of pharmacogenomics for effective pharmaceutical therapy, as well as the rise in popular scientific journalism [4].

The level of genetic literacy among physicians and other healthcare workers is significantly low. In fact, less than one-third of doctors (N > 10,000; response rate: 3%), who participated in a survey conducted in the USA, expressed confidence in their understanding of pharmacogenomics and its clinical applications; additionally, only one-eighth of doctors had recommended or ordered a pharmacogenetic test in the preceding six months [4].

A new paradigm for pharmacogenomics deployment in community pharmacy settings will be required by the introduction of pharmacogenomic testing directly to consumers. The pharmacogenomics implementation strategies used by community pharmacists today are largely reactive. (e.g., CYP2C19 genotyping is recommended when a patient has already been prescribed clopidogrel). The ordering of tests is done at the community pharmacist's recommendation by a health care provider [5].

The primary question of "Should I order a pharmacogenomic test for this patient?" is replaced with "What should I do with the test results in hand" by 23andMe's direct-to-consumer pharmacogenomic test, which opens up the possibility of preemptive testing. Because of this, when a patient and pharmacist engage, the cost of the test and insurance reimbursement are no longer factors, nor is the clinician's input in the choice to order the test in the first place [5].

Aim of study

This study is to investigate some of the most important ethical issues surrounding pharmacogenomic testing in community pharmacies as well as patient views regarding the practice.

Literature Review

An emerging technique to determine which people are more likely to benefit from or experience toxicity from medication therapy is pharmacogenetic (PGx) testing. According to the US FDA, 168 medications currently provide PGx information on the label. The best ways to give PGx testing to healthcare professionals are not clearly defined, even though the evidence supporting its ability to enhance health outcomes is growing. The delivery of these tests may mark the next development in pharmacy practice with the introduction of PGx testing. The viability and effects of community

pharmacist-delivered PGx testing have not been thoroughly investigated, despite the fact that pharmacists have participated in the adoption of PGx testing in clinic-based or hospital settings, frequently serving as a liaison between the testing laboratory and provider [6].

A subset of pharmacogenomics is called pharmacogenetics (PGt). It is described as "the impact of DNA sequence differences on medication response" and entails the study of single gene mutations. dose schedule customization for each patient. The European Medicines Agency (EMA) concedes that "pharmacogenetics might not hold the same significance for all medications." However, given the genetic variation among people, it is crucial to have a better knowledge of the identification of pertinent risk variables for medications for which PGt is significant due to its pharmacokinetic variability [7].

Healthcare workers and researchers should prioritize providing valuable testing while adhering to the four core principles of healthcare ethics: autonomy, fairness, beneficence, and non-maleficence. This will help them to respect the person [8].

The way that Tomaselli defines person-centered care has clear implications for drug selection. According to Hillman et al., a person's attitudes and behaviors regarding the use of medications are influenced by their experiences with medications as well as how they relate to health conditions that have affected themselves, their family, or influential others. When considered as a Venn diagram (figure 1), the meeting point of bioethics, pharmacogenomics (PGx), and an individual's drug experience is

where true "person centered" pharmacological treatment decisions are made [9].

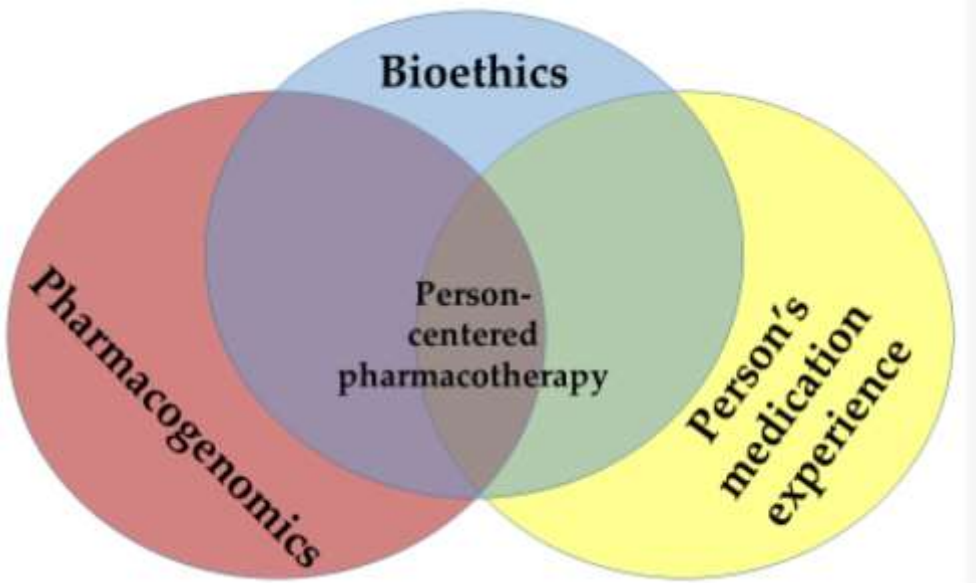

Figure 1 Pharmacogenomics, a Person's Experience with Medication, and Bioethics in Context [9].

There are notable overlaps in the Venn diagram between the corresponding dyads. significant moral concerns for patients, medical professionals, and society are concurrently brought up by the developing fields of genetic testing and PGx [9].

The relationship ethics factors of environment, uncertainty, embodied knowledge, reciprocal respect, and involvement can also impact and be changed by an individual's experience with medication. Lastly, a person's genetic makeup may have a significant impact on how they respond to drugs [10].

Bioethics Considerations Related to Pharmacogenomics

Privacy

Since traditional diagnostic genetic testing—which determines if a person has a hereditary condition or is at risk of acquiring one—and PGx testing—which examines how a person's body processes medications—have certain similarities, there may also be some related privacy issues. When deciding whether to have diagnostic genetic testing done, an individual has the right to make educated,

autonomous decisions about who can access their genome information, including researchers, social agencies, employers, insurers, and spouses [11].

On the other hand, PGx testing is different from diagnostic genetic testing in that it is not meant to, and typically does not, provide information regarding an individual's likelihood of contracting a specific disease. Compared to diagnostic genetic testing, PGx testing poses less privacy problems because it is not used for diagnosis [11].

Legally speaking, In 2008, the Genetic Information Nondiscrimination Act (GINA) was enacted in order to shield American citizens from discrimination when applying for jobs or health insurance because of their diagnostic genetic or PGx information. The Health Information Portability and Accountability Act (HIPAA) of 1996 was modified by GINA in 2013 to make it clear that genetic data is considered health information. Thus, genetic data exchange and usage are governed by the same HIPAA regulations as other protected health data. Moreover, it is forbidden for employers to charge higher premiums for health insurance policies they provide to employees if genetic testing reveals a pre-existing ailment [12].

Confidentiality

The ethical idea of secrecy is connected to protecting the privacy of a patient's genetic or PGx information. The ethical principles of faithfulness (the healthcare provider's), autonomy (explained below), and pledge not to share a patient's PGx information without the patient's consent, unless in extenuating circumstances), and right to privacy, as previously discussed, are the foundation forpreserving the privacy of PGx data about a patient. However, there are several circumstances in which patient data confidentiality cannot be guaranteed. When it is required to violate confidentiality in order to prevent substantial injury to others, the healthcare provider may do so ethically [13].

Autonomy

The ethical principle of autonomy, which holds that reasonable (competent) people should have the freedom to make their own judgments, is closely tied to decisional privacy. The idea of

"informed consent," which will be covered later in this article, is based on the idea that an individual must be fully educated about the possible outcomes of their choices in order to make an autonomous and well-informed decision. A person has the autonomy to decide who can access information regarding their genetic tests, as was mentioned in the privacy discussion. The experience a person has with medications also influences their own choices, such as whether or not to use a specific medication at a given time to treat a particular ailment [14].

Informed Consent

A cornerstone of person-centered care is informed consent. As previously mentioned, a competent person must be fully informed about the possible outcomes of PGx testing versus not testing, as well as the potential outcomes of various treatment options versus no treatment, in order for them to make an autonomous decision about getting tested for PGx and/or continuing with treatment. Not only does the individual sign a consent document, but they also receive education and have the chance to ask questions. This is known as informed consent [13].

Furthermore, informed consent shields the patient from parentalistic or paternalistic decisions made by the physician (feminine clinicians can be just as "paternalistic" as masculine ones). Instead of the physician forcing the patient to participate in these activities, the informed consent process is a tacit acknowledgment that the patient is engaging as an active partner with the provider in a shared choice about whether the patient will undergo testing or get treatment [13].

Respect for Persons

Respecting patients as individuals is one of the fundamental ideas of patient-centeredness. This core idea is founded on the ethics thesis of German philosopher Immanuel Kant, which holds that people should be treated with respect for their unique moral position and freedom to make their own judgments. A person's "personhood" is already somewhat lost when they become a patient, as they are frequently divided into groups based on factors like age, sex, clinical condition, race, and/or comorbidities. Based on a patient's genetic predisposition that may affect how they

respond to and metabolize particular medications, PGx offers an extra layer of classification [15].

The Pharmacist's Role in PGx Testing

Pharmacists provide a tremendous deal of specialized knowledge to the PGx testing conversation. As of the time of writing, pharmacists have a better understanding of the genetic factors influencing drug safety and efficacy than the majority of other healthcare practitioners. They have improved instruction regarding the genetic genesis of drug responses; since 2016, PGx instruction has been mandated in all pharmacy programs in the United States. Pharmacy values—which were previously discussed—put them in a great position to help prescribers take PGx test findings into account when making decisions about cancer therapies or warfarin dosage adjustments [16].

Patients might not always be aware of a pharmacist's competence in this area, but pharmacists are also in a great position to educate patients regarding PGx testing. In order to be as effective as possible in the position of "PGx counselor," pharmacists must talk to patients about PGx testing within the framework of their drug history [16].

Equity and Access

Pharmacogenomic based clinical decision support (CDS) implementation has the risk of exacerbating healthcare inequities if the limitations of the available pharmacogenomic data are not carefully considered and deliberate attempts are not made to address them. A shift in public policy and insurance practices to guarantee that pharmacogenomic testing is available to all patients regardless of socioeconomic status, an ethical commitment to health justice, and the inclusion of diverse research participants are all necessary to ensure that pharmacogenomics improves health equity for all rather than escalating inequalities [17].

A number of issues with healthcare delivery that have previously resulted in disparities in care can be resolved by pharmacogenomics. Instead of relying on population averages or empirical observation, it promises to personalize and target medicine selection and dose based on the genetics of each

particular patient. In less time and with fewer visits to the doctor, CDS tools assist practitioners maximize patient care by streamlining decision-making around the utilization of pharmacogenomic tests [17].

Pharmacists Training

In their professional programs, many practicing pharmacists have only rudimentary training in pharmacogenomic medicine. While pharmacogenomic curricula development is supported by pharmacy professional societies and schools, particularly for incoming students, there are few Grants for clinical pharmacology training, fellowships, and postgraduate specialized pharmacy residencies are all available nationwide for advanced pharmacogenomic education. Previous assessments of active pharmacists also highlight the significance of incorporating into practice overall [18].

85% of responders to a survey regarding the educational needs of pharmacists felt that pharmacogenomics knowledge should be mandatory for pharmacists. On the other hand, 63% of participants said that it was impossible to reliably use the findings of pharmacogenomic tests for pharmacological therapy selection, dosage, or monitoring. The Royal Dutch Association for the Advancement of Pharmacy-Pharmacogenetics Working Group (DPWG), the Canadian Pharmacogenomics Network for Drug Safety, the Clinical Pharmacogenetics Implementation Consortium (CPIC), and expert practice groups within medical societies are just a few of the groups of experts that have come together tosupport the practical application of pharmacogenomics [18].

Clinical Decision-Making

Not only must technology be modified for the clinical translation of genetic data to be successful, but behavioral acceptance into the clinical decision-making process is also crucial. Our results showed psychological enactment barriers (lack of familiarity, inertia of prior practice) and practical barriers (point-of-care availability, physician time restrictions) may both be overcome. Specifically, through the use of physician electronic medical record (EMR) documentation, researchers found a recurring theme suggesting that the primary driver of prescribing behavior change among our early adopters was outcome expectancy—the belief that a

particular behavior will result in a particular consequence. Put differently, doctors were very likely to use genomic information when prescribing if it increased the chance that side effects might be prevented or that treatment responses could be improved. Adoption is more likely for a pharmacogenomic variation with a stronger cause-and-effect link [19].

Counseling and Patient Education

Prior to PGx testing, family history must be noted, the patient's natural history of the illness must be documented, and medical records must be obtained to support patient reports. Several delivery methods include a way to tell the patient about the testing possibilities and implications (pretest) after it is determined that a PGx test could be beneficial. Joint decision-making between the patient and the physician can direct the pursuit of testing when the patient is aware of the advantages and drawbacks of the procedure. If the patient consents to testing, it is best to discuss the interpretations and conclusions of the findings with the treatment team and the patient in order to decide whether the medication schedule needs to be adjusted [20].

After the test, other details can be shared, such as secondary findings suggesting illness risk information or risk to family members (posttest). on patient education on PGx testing and the precautions that should be taken to reduce injury or misunderstanding, no agreement has been reached. Furthermore, it's debatable whether more discussion is needed to determine precisely what information—if any—or potential hazards should be disclosed [20].

Ethical Marketing And Advertising

Its primary objective is to design and oversee the provision of a good or service that will meet certain demands by being accessible at the appropriate time, location, cost, and with the appropriate personnel. Patients, medical professionals, and physicians are the target audience for genetic testing. For certain groups, alternative strategies need to be chosen and implemented [21].

Physicians should be well informed about the advantages of using genetic tests for both reasoned drug prescription and use that can reduce the risk of adverse drug reactions in patients as well as for

the early diagnosis of hereditary disorders. Similar to this, patients should understand the advantages of undergoing a genetic test and customized treatment plans, as a person's genetic profile can provide important insights into their health results [21].

Additionally, early diagnosis of a hereditary condition will increase the importance of prevention, save future medical expenses, and—above all—improve people's quality of life. Genetic test direct marketing strategies that are frequently employed to reach the general population, such as newspaper and television commercials, cold calls, and bulk postal or email correspondence, are seen to be unsuitable for this kind of specialist service. It is crucial to hire qualified biomedical experts as marketing personnel before promoting a genetic test in order to give consumers all the information and direction they need in an appropriate and scientifically acceptable way [21].

Pharmacogenetic testing increased the number of patients with current drug modification possibilities by 38% when compared to routine medication review. It also provided useful genetic information that could be referred to in the future to customize prescribing decisions for all patients [22].

Conclusion

Informed consent, privacy and confidentiality, equity and access, accurate result interpretation and communication, integration into clinical decision-making, ethical marketing practices, and long-term follow-up are some of the ethical issues surrounding pharmacogenomic testing in community pharmacies. Following these moral guidelines can assist improve patient outcomes and guarantee that pharmacogenomic testing is implemented responsibly in community pharmacy settings. A new and exciting era in medication prescription and healthcare in general is marked by pharmacogenomics, which should be embraced with measured enthusiasm and cautious responsibility. There are undoubtedly many methodological and ethical barriers preventing the widespread clinical application of pharmacogenetic testing.

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