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Pharmacogenomics in Clinical Practice: Educating Nurses and Integrating Lab Data

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ABSTRACT

Pharmacogenomics is the study of how genes affect a person's response to drugs. It utilizes information about a person's genes to inform the selection of medications and their doses. Pharmacy providers are increasingly being asked to advise on pharmacogenomic matters based on genetic testing ordered by prescribers or patients themselves. Pharmacogenomic education is essential for training competent providers and helping them remain up to date.

Now, major medical laboratory companies have pursued partnerships with well-known labs to offer pharmacogenomics testing services directly to the patient and prescriber via advertising to primary care providers and patients. Furthermore, testing has began to be offered through the genomic profile matched to the cancer via a molecular tumor board. In oncology, this testing would result in pharmacogenomic data as well, which could be even more complex considering the number of medications chosen. Pharmacogenomic test results can impact a medication that the patient was previously taking and whether it should be stopped, optimized, or potentially replaced. Integration of pharmacogenomic prescribing into clinical practice remains variable, and integration into some practice settings or chronic disease states is more challenging. Considering the number of available pharmacogenomic-tested medications combined with the number of medications currently prescribed, the number of patients treated, and the current understanding of pharmacogenomics, it is clear that such an endeavor is a daunting task for current healthcare providers with likely inadequate informatics and familiarity with pharmacogenomics (W. Guy et al., 2020). However, if each provider pursued education and training, this patient care enhancement could be achieved. Identifying best practices for educating health care professionals and trainees across disciplines on pharmacogenomics is vitally important for the continued growth and sustainability of pharmacogenomic services.

Keywords: biopharmaceuticals, medicine, therapeutic proteins, monoclonal antibodies and precision medicine Unlike traditional small molecule drugs

1.2 1. Introduction to Pharmacogenomics

Understanding prescribing medications is a cornerstone of nurse education and comprehensive medication management process. As pharmacogenomics becomes a standard of care, there is an increasing necessity for nurses awareness of pharmacogenomics. Education on the clinical application of pharmacogenomics in relation to medications with available genetic testing is imperative (W. Guy et al., 2020).

Pharmacogenomics, the study of how genes affect a person's response to drugs, is a growing area of importance for clinical care. Specifically addressing drug-induced pharmacogenomics, one of the best-studied effects of genetic variation on therapeutic efficacy and adverse drug effects is the cytochrome P450 (CYP450) system, a large family of Phase I metabolic enzymes. Informed by new evidence regarding medications, there are several drugs with existing knowledge that might be integrated into clinical practice (J. Karczewski et al., 2012). These are the FUT2 gene and drug (rimantadine), VKORC1 gene and drug (warfarin), cardiac biomarkers (CYP4F2 gene and vitamin K epoxides), HLA B5701 and ABCC1 and abacavir, and HER1 and drug (panitumumab).

Identifying best practices for educating a diverse set of healthcare professionals about a rapidly evolving area is vitally important for the continued growth of services that include pharmacogenomics. Many medications have pharmacogenomic evidence and drug labeling. Several newer medications approved by the Food and Drug Administration are beginning to gain attention in provider and payer markets with increasing availability of genetic testing. Pharmacogenomic testing may optimize medication selection and/or dosing to achieve the desired therapeutic outcome or reduce the risk for an adverse effect, supporting safe and more effective patient care. The literature supports the clinical application of genotyping drugs with pharmacogenomic labeling, and applying genotype-guided dosing for several FDA-approved medications may help yield beneficial changes in clinical outcomes.

1.3 2. Importance of Pharmacogenomics in Healthcare

Pharmacogenomics is the merging of pharmacology and genomics, focusing on how genes affect a person's response to drugs (W. Guy et al., 2020). The Public Health Genomics Genomic Data Sharing Policy encourages the use of genomics in clinical practice with a focus on translation to improve population health. Patient care was initially limited to large academic centers, but access to genomic data is ubiquitous and readily available. Many medications are now FDA-approved and commercially available with pharmacogenomic labeling, however establishment of clinical pharmacy services and development of a framework for consideration of use of pharmacogenomic data in therapeutic decision-making for select medications has not yet been developed. Initial pharmacist-led medication-centric stewardship of pharmacogenomic data is vital in this effort. The need to identify best practices for education on pharmacogenomics is vitally important for health care professionals, as current education is inconsistent and often inadequate. These standards will help clarify which paradigms are most effective in integrating pharmacogenomic considerations into customary therapeutic decision making and help build a trained workforce to meet the increasing demand for pharmacogenomic services. Patients may ask providers about pharmacogenomic information for medications with a pharmacogenomic label. Many patients

have already had genotyping completed for polygenic chronic disease risk scores such as for type 2 diabetes or other currently unvalidated tests available for consumer purchase. Demand for pharmacogenomic information regarding genotyped or medications with a pharmacogenomic label will rise, due to the generation and dissemination of cheaper WES or WGS. The skillset necessary for health care professionals to meet this need is different from that needed for traditional genetic testing analysis, but is critical if the promises of pharmacogenomics are to be realized in practice. As a component of future workforce development, currently practicing pharmacists must become proficient with pharmacogenomics in medication therapy management or other practice areas to adequately educate and inform patients.

1.4 3. Current Trends in Pharmacogenomics Research

Pharmacogenomics is the identification of genetic variants (variants) individually or collectively influencing the pharmacological response to a given drug. As the use of high-throughput technology increases, the assessment of many genetic variants is now feasible, and as a result, the incorporation of pharmacogenomics into clinical practice is growing (W. Guy et al., 2020). Pharmacogenomics is increasingly recognized as a vital test for pharmaceutical care. With the use of pharmacogenomic data alongside other routine evaluations, patients are anticipated to improve clinical outcomes and avoid adverse medication events. Conversely, the absence of pharmacogenomic results (such as allele copy number and type information) may result in inferior pharmaceutical care and worse clinical outcomes. In particular, available genetic tests with detailed annotations are needed for the seamless use of pharmacogenomics in practice. However, their application to patient pharmacotherapy is largely setting- and clinician-dependent, and framework services to facilitate their application are generally lacking.

The aim of the study is to establish a framework service—a pharmacogenomic interface running on a laboratory information system—to facilitate the use of pharmacogenomic data for medication treatment recommendations. A pharmacogenomic microlibrary containing tests that request for any commercially acquired test is built to launch the pharmacogenomic interface. To provide genotypes and phenotypes of the pharmacogenes tested, supporting data sources are integrated into the interface. Finally, a personalized medication treatment recommendation system is built in the chassis of the pharmacogenomic interface, along with tests-example details. This service is executed in an example clinical setting to aid clinical professionals in delivering personalized care rapidly and efficiently. The above technical prototypes are deployed in an operational server to facilitate multi-institutional testing, recommendation, and further implementation of the pharmacogenomic interface. Optimized extensively in parameters and settings, the pharmacogenomic microlibrary generates infinitely scalable testing services.

Pharmacogenomic tests, along with their respective genotype-phenotype conversion definitions, are preserved in an application programming interface (API) based on the FastAPI framework for other systems to retrieve all current pharmacogenomic tests. The pharmacogenomic interface can be easily incorporated into any existing laboratory information system, allowing the display of pharmacogenomic results in patient charts within minutes. Auto-generated detailed medication treatment recommendation reports can be sent to clinicians via secure messaging for review and

act. Integrations with various APIs of genetic testing companies make recommendations available even before the test result is accessible to clinicians. This service potentially changes the paradigm of pharmacogenomic practice.

1.5 4. Pharmacogenomics and Personalized Medicine

Pharmacogenomics (PGx) is the study of the impact of genetics on an individual's response to therapeutically relevant chemicals, such as medications. One main goal of PGx is to provide rapid and affordable genetic testing that will allow healthcare providers (HCPs) to tailor a patient's medication therapy. This can ultimately improve patient care or drug efficacy, reducing adverse effects associated with traditional treatment plans (W. Guy et al., 2020). Clinical PGx has emerged as a growing field that provides clinically actionable genetic testing services. However, healthcare providers require additional education and training to understand how to apply these new tests to improve patient care. In addition, laboratory partners must develop software solutions that will integrate lab-generated PGx data into electronic health records (EHRs).

Studies have shown that genetically guided dosing protocols can improve efficacy and safety of warfarin and clopidogrel therapy; and new clinical trials are assessing the effectiveness of a broader range of drugs. However, one recent publication noted that, for a variety of drugs, only 14% of their clinical effectiveness was found on the basis of 16 candidate SNPs. Pharmacists must thoroughly understand the current evidence in the literature, especially for preemptive testing, the federal regulation of testing, the clinical utility of currently available testing options, and the educational and clinical challenges facing the profession. Information on how such knowledge could impact pharmacy practice and the education of fellow healthcare providers must also be communicated to audiences with varied levels of PGx training. Some options for receiving PGx education include presentations to pharmacy students, residents, and HCPs; CE lectures; and articles for pharmacy journals. Continuing education units must be available for HCPs requiring certification. Additional training opportunities include PGx mentoring, as well as trial experiences involving PGx.

In this rapidly evolving field, PGx courses are becoming available at some pharmacy schools across the country, but most programs require students to improve their confidence and competence. Creative course materials addressing these areas can be developed by gathering details from educators who are successfully teaching PGx content. Employing peer activities is an effective way for students to master course material and will allow them to engage in high-quality interactions with others in experimental learning situations. In addition, elements of active learning such as video and audio case design are powerful tools to teach PGx. The Formative Assessment of Learners' Engaged-in-Science Learning Environment questionnaire can be valuable in evaluating the impact of course design, particularly their development in multi-university collaborations.

1.6 5. Role of Nurses in Pharmacogenomics

Pharmacogenomics (PGx) is an exciting area of study to educate clinical nurses and prepare them to provide a plan of care based on medication genomics (W. Guy et al., 2020). The clinical application of pharmacogenetic testing can optimize medication selection and dosing while

minimizing adverse drug reactions, but nurses are often unaware of this information. The implementation of genetic tests into clinical practice and electronic health systems requires a concrete plan. The bottlenecks are mainly lack of education/training for healthcare professionals in PGx implementation and interpreting clinical interpretation report (CIR). Nurses are best suited to educate clients about PGx, however, very few studies are focusing on the education needed to implement PGx. The project aims to create an education resource for future nursing students about PGx focusing on the use of medication genomics in providing a specific medication plan concurrent with integration of laboratory data into clinical information systems (CIS) including electronic health records.

This work incorporates laboratory data into CIS providing clinical decision support (CDS) for physicians and nurses, with the potential to improve patient outcomes through the delivery of safer and more effective prescription. Modern laboratory data automation, together with advancements in the digitization of healthcare records, has enabled fast and efficient preparation for the integration of laboratory data into such systems. Integration of clinical data into CIS in recent years has revolutionized healthcare, allowing for automatic provision of decision support to physicians while conducting patient assessments and diagnoses. This has enabled improved reliability of treatment recommendations, which has been shown to reduce mortality in mental health hospitals and increase adherence to guidelines in oncology. However, the interpretation of laboratory test results, crucial for providing recommendations, is still faulty. Methods for automated interpretation of laboratory test results are still lacking, preventing practical integration of laboratory data into such systems. This presents an opportunity to address a pressing need in the clinical community.

1.7 6. Educational Needs for Nursing Professionals

One barrier to the implementation of pharmacogenomics into routine clinical practice has been the education of pharmacists and other health care professionals. Although these health care providers clearly perceive a lack of evidenced-based recommendations that are sufficiently useful for their ordinary workflow, they may also find themselves less confident about making recommendations. As a result, they may make fewer or no recommendations — and ultimately ignore PGx altogether (W. Guy et al., 2020). Academicians and professional pharmaceutical organizations have developed several options to educate both pharmacists and student pharmacists on the basic tenets and application of pharmacogenomics. These efforts ranged from free online continuing education modules to large-scale programs that involve multiple institutions and pre- and post-tests for program participants. The American Society of Health-Systems Pharmacists has charged pharmacists with spearheading the clinical application of pharmacogenomics. In a statement to their membership, ASHP called on Boards of Pharmacy and Colleges of Pharmacy to include curricula on PGx to enable pharmacists to recommend appropriate genetic testing, tailor drug therapy based on test results, and provide education to other healthcare professionals. To incorporate appropriate new knowledge into existing programs, it is anticipated that all pharmacists will need some baseline level of PGx training, with some requiring advanced training in the area. In this regard, best practices endorse training for both pharmacists and students to

advance pharmacist skills in this area in the future. Access to foundational and advanced knowledge about PGx and making training opportunities available on how to learn will ensure that pharmacists maintain this knowledge as new technology and processes emerge. Leveraging flexible methodologies and learning strategies, including asynchronous formats, will allow pharmacists to quickly and easily access this information. One method to enhance training in the area of PGx is through easily accessing continuing education courses.

6.1. Curriculum Development

The integration of pharmacogenomics (PGx) into clinical practice remains an ongoing challenge. In particular, a lack of knowledge on how to apply PGx test data in the context of drug therapy management has limited the practice impact of this hot topic. On top of improving the knowledge foundation of PGx and actionable test results being ready through the activity, ongoing efforts were devoted to focusing on PGx application. Specifically, a systematic approach of educational intervention is refined based on the initial train-the-trainer model and a large number of practice case scenarios are developed with a trajectory that mirrors how PGx is integrated into clinical practice in general. The case scenario development process and example case scenarios can serve as scaffolding to similar educational efforts focused on PGx in other settings, such as pharmacy and laboratory medicine.

As the utilization of PGx tests increases, there may be greater demand for PGx-related lab services. Understanding the backgrounds of whether and how PGx test data are being utilized in prescription drug therapy management can help better define gearing education interventions to facilitate PGx application. Such educational efforts should target nursing staff and actively identify effective methods to support their performance. It remains to be seen how delivered education interventions will affect the nursing staff and medication-related clinical outcomes in the PGx testing population in the long-term after facilitating education for nurses. Further studies in a more diverse population with longer duration of follow-up may be valuable and informative. Moreover, it will be interesting to investigate the effect of integrating nursing education with consumer education interventions on patient trust in and attitude toward using prescription drug therapy recommendation based on PGx test data.

Developing educational interventions according to an adult and continuing education model inherently builds a culture that values research, innovation in pedagogy, and continuous quality improvement. As PGx has arrived in clinic and initial PGx education interventions to support its application are developed, future studies may be focused on closing the knowledge gap on how to interpret and apply PGx test data. On a basic level, targeted learning objectives can be identified and applied to guide content development. It will be helpful to investigate candidate instructional strategies that suit the curriculum and learning objectives, and to evaluate the effectiveness of educational interventions. Moreover, developing quality PGx practice cases to accompany it may be informative for educational efforts in other settings and professional disciplines. PGx in clinical pharmacy can bring immense benefit to the optimization of medication therapy management and holds great promise for improving patient outcomes.

6.2. Continuing Education Programs

The development of healthcare providers who understand and translate pharmacogenomics testing into clinical practice is vitally important for its widespread acceptance. Educational initiatives are essential for implementation and the authors of this chapter have developed programs for pharmacists, nurses, and physicians. These programs are intended to reach all healthcare workers who want to advance their knowledge of pharmacogenomics and its relevant application to practice. In collaboration with the University of Toronto, training papers were developed for continuing education that offered pharmacogenomics case studies and online modules. Data were collected pre- and post-module to gauge knowledge shift. Teaching and knowledge transfer can occur on many levels; in a variance in perceived understanding of pharmacogenomics and its clinical relevance before and after module completion, similar data collection counseled testament of program effectiveness (Crown et al., 2020). In Canada, the accreditation of continued education programs is offered through the Canadian Council on Continuing Education in Pharmacy (CCCEP). Accreditation is voluntary and extends for five years upon review of the program and data outcomes. To date, one pharmacogenomics continuing education program for pharmacists has been accredited by the CCCEP and has approved up to 50 providers to offer regional programs. Approximately 1,200 pharmacists have taken the accredited modules once, but many continue to attend local events. On a smaller scale, a lesser program focused on case studies was developed and presented across many Canadian healthcare institutions. Personal programs to educate groups of healthcare providers specifically about pharmacogenomics have also been developed and offered. In addition to these ongoing offerings, many health providers are working to develop and embed pharmacogenomics curricula within formal education for healthcare providers across health disciplines to further systemic acceptance.

1.8 7. Integrating Pharmacogenomics into Clinical Practice

Health care providers must consider the impact of genetics on drug selection and dosing to optimize drug therapies in patients, specifically generalist-level knowledge and tasks appropriate for a registered nurse role (W. Guy et al., 2020). This included pretest patient history/review, pharmacogenomic education, first-dose recommendations at point of care, and follow-up monitoring. Pharmacogenomics are commonly performed with patients undergoing clopidogrel or warfarin therapy, and education materials were derived from existing resources. The final training included an overview of pharmacogenomics, implications for drug selection/dosing, case studies, and sample patient interaction scenarios. Subsequently, a randomized clinical trial was launched to assess the impact of the training on patient care and provider knowledge toward pharmacogenomics.

Although pharmacogenomics improve clinical care by providing health care providers with actionable, easy to understand, and applicable patient history information, these databases are rarely accessed by providers without research training or having dedicated resources. Pharmacists can play an important role in integrating pharmacogenomics into local practices through physician education, developing education tools for other providers and patient education, utilizing the databases in routine care, and creating a framework for decisions based on pharmacogenomics

data. Education and system processes at the institutional level facilitate timely access to pharmacogenomic information and suggestions internationally. Initial educational sessions led by pharmacists with expertise in pharmacogenomics are critical to provide knowledge to other health care providers. Simple, intuitive, and relevant education materials should be developed so providers feel comfortable using pharmacogenomics. The nursing research team met with an academic pharmacist to understand the clinical significance of clinical claims and implications in patient care.

The search strategy was written for PubMed's standard search features to capture the latest and most relevant pharmacogenomics information immediately. In many situations, it is inappropriate to change a patient's therapy or initial dosing because an alternative medication was not used during drug trial periods. It is impractical to quantify where in a entire patient databases the cases should return to ethically correct easy-to-implement scenarios. Pharmacogenomic databases have not been translated to a generalist level to centralize knowledge, responsibilities, and tasks that were appropriate for a registered nurse. Expanding the involvement of nurses in the clinical and research applications of pharmacogenomics in these areas could benefit both patient care and this growing field. Involvement in pharmacogenomics require strong systems of care by the institution. Each of these tasks requires policies and procedures for implementation and shared corrections.

7.1. Clinical Guidelines

Clinical practice guidelines are essential to ensure the safe and effective conduct of clinical pharmacogenomic testing (CPGT) and the proper interpretation and reporting of genetic test results. Pharmacogenomic testing clinical practices should be continually updated based on newly published literature and new drugs being investigated (Kim et al., 2016). Systematic reviews should be periodically conducted, focusing on evidence development for the gene-drug pairs, preanalytical factors influencing pharmacogenetics, or genetic variants that are more applicable to an ethnic population.

Educational activities on the clinical significance, benefit, and basic knowledge of pharmacogenomics are necessary for health care professionals. Pharmacogenomic guidelines or clinical recommendations must be made readily available, freely distributed to laboratories, and fit into the local/regional clinical situation (A. G. Agúndez et al., 2014). These efforts are essential to properly utilize pharmacogenomics for the improved benefit of patients, starting from the establishment of transparent lab-based pharmacogenomic testing for clinicians.

7.2. Decision Support Tools

Recognizing the crucial role of education in integrating PGx in clinical practice, various education programs for nurses, genetic counselors, and pharmacists have been developed through interprofessional collaboration. An important barrier to PGx education is the rapid evolution of PGx. A fall-off in learners' confidence when PGx knowledge, skills, and clinical application are assessed later following an education program suggests that PGx knowledge is not retained well. While continuous education over the years is potentially an effective way to overcome this barrier, it cannot proportionately augment the overall education workload of clinical pharmacy. Educators, therefore, must decide on optimal instructional tools and content to facilitate long-term learning

and clinical application of PGx by nurses. Similar topics could also apply to the education of healthcare professionals for PGx implementation in clinical practice in other countries. PGx implementation and education in entry-level nursing programs is understudied. Research should focus not only on the current state of PGx education but also on identifying efficient instructional tools and content for long-term and effective learning of PGx by nurses.

Translating PGx knowledge into clinical action requires decision support tools for healthcare professionals, objective lab test reporting, and integration of educational and clinical decision support tools. Directed by the report of the PGx pharmaceutical lab to the physicians, the nursing support tool provides practical and explicit information about the meaning and clinical applications of PGx results. Three studies have evaluated various decision support tools for PGx in clinical practice. One study analyzed both user feedback and usability specifications of a pocket card on clinical PGx decision support tools and their evaluation by healthcare professionals who participated in clinical PGx implementation (Blagec et al., 2016). The second study assessed the diagnostic performance and clinical relevance of a generically applicable laboratory PGx report to recommend psychiatric drug treatment decisions and its feedback from physicians and clinical pharmacists. Evaluating the acceptance and practical use of PGx decision support tools is of paramount importance for enhancing their usability and integration into clinical practice.

1.9 8. Laboratory Data Interpretation

The pharmacogenomics knowledge of nurses is integral to the successful implementation of pharmacogenomics in practice. Inequities persist within healthcare systems that exacerbate the disparities of patient populations in clinical pharmacogenomics (W. Guy et al., 2020). This describes a nurse-led initiative that investigates the education of nurses in pharmacogenomics and the integration of lab data within clinical systems to create linguistically accurate pharmacogenomics recommendations that can be accessed, interpreted, and utilized within electronic health records across nursing practice in partnership with laboratory experts.

Critical areas in the clinical implementation of pharmacogenomics include education, incorporation of genetic variant interpretation along with laboratory data into the EHR, and ensuring equitable access to pharmacogenomics services. There is also a need to offer health literacy education specific to pharmacogenomics and its implications for health. Nurse practitioners and clinical nurse specialists across all specialties are uniquely positioned to guide health literacy efforts and improve pharmacogenomics integration across systems of care.

In 2020, a collaborative team of nurse practitioners, clinical nurse specialists, laboratory experts, pharmacy experts, an implementation scientist, and diverse stakeholders and patient populations convened, with particular consideration of health equity and simultaneously addressing communities of color that have been historically underrepresented in research or underserved by the healthcare system. A series of focus groups and semi-structured interviews revealed that inequities persist in adopting pharmacogenomics practices in diverse healthcare settings, and more efforts are needed to inform communities about pharmacogenomics and provide equitable access to services. Stakeholders prioritized educating and upskilling nurses across diverse specialties and settings regarding pharmacogenomics. Strategies that integrate genetic variant interpretation

within the EHR to ensure clinical pharmacogenomics recommendations are culturally and linguistically aligned with patient populations were viewed as equally important. Initial efforts in these two areas were undertaken through collaborations led by nurse experts, laying the groundwork for multidisciplinary research teams and collaborations to ensure the sustainability of these efforts within healthcare systems.

8.1. Understanding Genetic Testing Results

The emergence of COVID-19 has accelerated the growth of telehealth services. Various professional and practice guidelines have been adopted during the pandemic, including those for the usage of telehealth in nursing practice. Although practice guidelines and recommendations have changed to help manage COVID-19, there are many lessons learned throughout the pandemic that will likely carry forward after it is over. Understanding opportunities for improvement and demand for change in telehealth services by applying a formal telehealth maturity model is critical for maintaining the benefit of telehealth services beyond COVID-19 and advancing optimal care delivery using telehealth (W. Guy et al., 2020).

The COVID-19 pandemic has precipitated many profound changes in healthcare that are fundamentally altering the fabric of care delivery throughout the world. Telehealth is one of the most dominant changes that has occurred during the pandemic, as healthcare systems have adopted virtual solutions to enable safe and efficient delivery of care to patients. Telehealth encompasses a constellation of technologies to share patient information over digital channels to enhance communication and facilitate consultations remotely. Given the highly contagious nature of COVID-19, contact precautions were implemented to mitigate the spread of the virus. In-person visits were postponed for patients with non-urgent concerns, which resulted in a significant mental health crisis and increased adverse outcomes prior to the expansion of telehealth services. Technology-enabled solutions were rapidly deployed to allow for the continued delivery of many services to patients who otherwise may have postponed care. Data have demonstrated the effectiveness of telehealth in delivering healthcare services across various disciplines, including psychiatry, obstetrics/gynecology, primary care, etc. Recommendations and guidelines for adopting telehealth technologies were built upon the fundamental importance of the training of workforce on these new technologies, enhancement of workflows for delivery of care, and consideration of regulations and professional standards to govern this new mode of care delivery.

8.2. Communicating Results to Patients

Generating knowledge and addressing health literacy empowers patients to engage in their care. Increasing evidence highlights the need to tailor explanations of pharmacogenomics to patient characteristics such as education level and ethnicity. Using the lollipop model decreases complexity without loss of accuracy. An assessment of patient perspectives on pharmacogenomics educational materials shows that many materials inadequately addressed health literacy and comprehension.

Research on how best to communicate pharmaceutical genomic results to patients is limited. Key principles reveal that understanding is a prerequisite for empowerment regarding health. Generating knowledge, a social cognitive process influenced by context, moves from awareness

to an appreciation of implications. Patient-centered communication and shared decision making are critical to ensure that new powerful diagnostic tests normalize genetic factors and that patients engage in motivational processes to implement recommendations. Based on sound cognitive and behavior change theory, multidimensional assessment of patient factors can tailor presentations to the individual's characteristics and circumstances.

Pharmacogenomic results can be expressed in quantifiable fit for use or probabilistic terms but evidence is lacking to guide practice communication based on these formats. Describing the clinical impact with examples that vary in clinical significance increases understanding and appropriately regulates expectation. Education on how to extract and integrate risk data into clinical significance across regulatory, clinical, and economic parameters is critical. Training patients and their advocates to present thought-through alternative interpretations, questions, and decisions in advance of interaction with professionals signaled to be unprepared for a data flood is important.

The greatest task remains how best to communicate genomic results and pharmacogenomic intent to patients. Pretesting the impact and interpreting knowledge and acceptance via independent questions is requested. To identify and disseminate research priorities on PGx result communication to patients is called for. Approaches to use PGx in pandemic vaccination and public health are detailed.

1.10 9. Ethical Considerations in Pharmacogenomics

At this time, no guidelines exist that make general recommendations of 1 gene panel over another. Therefore, testing choice is remaining in the physician’s hands and often selecting the wider panels are favored due patient or physician preference. Other factors for standardization include establishing standards for verification of the testing companies. This should also include development of educational programs and partnering with pharmacogenomic testing companies in order to ensure proper laboratory test and interpretation understanding. Ultimately, there must be ongoing education and review of the system’s pharmacogenomics practices in order to consider current research advancements, testing company options and improved institutional practice. In addition, it is important to integrate these processes in other laboratory testing, such as when dietary analysis is in the consideration in patient population with many co-morbidities involving food intake and other drug-drug interactions.

Data management is increasingly becoming an issue to consider when results are shared via the electronic health records (EHR) for both the provider and the laboratory. Vicious contradictions against gene thinking along with non-gene thinking must be addressed rigorously with a focused multidisciplinary effort on coordinating translational pharmacogenomics research to clinical practice. Ultimately, there are limitless ideas of using pharmacogenomics in practice but simply put, it must be integrated at the prescriptive level through the EHR. Thought must be given to what anesthetic method is chosen, what drug focus, and the model and purpose. The future is bright for the 21st century healthcare provider as there will be exciting advancements in understanding pharmacogenomics for better patient care. The overall focus will be on addressing barriers while

building pathways that are easy to integrate into routine clinical practice in the greater healthcare context (W. Guy et al., 2020).

9.1. Informed Consent

Testing for pharmacogenomic (PGx) variants is an integral and evidence-based part of personalized medicine. PGx testing informs healthcare providers on drug-drug and gene-drug interactions (GDI) to reduce the risk of adverse drug reactions and increase drug efficacy. However, patients often lack comprehension of what PGx testing means, how it happens, who is involved, and what the results mean. Screening for severe mental illness (SMI) is rare in the pediatric population, even those who enter the juvenile justice system, where youth with serious behavioral challenges typically flow to. This, combined with lack of attention to other potential social determinants of health (SDOH) and mental health, leads to missed opportunities for screening and addressing treatment barriers in juvenile justice youth mental health care.

Informed consent (IC) is a process of information exchange between a health care provider and patient, typically about the risks, benefits, and alternatives of a specific procedure. It is generally viewed as a patient's right, rooted in medical ethics and related to respect for autonomy. However, PK testing requires patients' willingness to accept potentially unexpected results due to its broader effects on the family, self, and relatives. Additionally, informing patents can be a challenge, as the patient population is usually overwhelmed due to the disease severity and the systematic components of acute care. Many patients were confused about terminology and possible mechanisms of IC. Overwhelmed emotional response can impede comprehensiveness by blocking the responsible brain area. Notably, urology patients with IC uniformity did not exhibit better comprehension. Efforts to provide additional and accessible educational material to educate patients showed limited improvement. Frustrations were expressed in multiple forums about the limits of informed consent.

When the patient population and public health narrative vary, BBI members believed clinicians play a vital role in decision-making. Facilitated consent with a "team approach" would protect patients from being overwhelmed. Although clinicians did acknowledge the expectation of tailoring the conversation to the patient population, it remains unclear whether this is widely achieved. Variation in IC was observed across health systems and institutions. Many IC forms were highly technical, formatted poorly, or only available in English. The exploration of designing ongoing interventions to improve understanding and foster trust in a fast-changing healthcare landscape is warranted (Pereira et al., 2024).

9.2. Privacy and Confidentiality

Privacy concerns about genetic methods or results are well founded. Genetic information is regarded as highly confidential and relates directly to the core of most people's identities (E. Lunshof et al., 2008). For this reason, health data, and especially genetic data, are theorized as being unique and unlike other types of personal information. Unlike HIV information with relatively definite symptoms, genetic predispositions are silent for long periods of time; result in many uncertainties for the patient; and direct consequences can affect not only the patient but their family, descendants, and distant relatives. Genetic data relate to and explain some of the internal,

immutable characteristics of patients. Associated with an elevated risk of future disease, the 'genetic barrel' is perceived to be a Pandora's Box with potentially catastrophic consequences. Privacy and confidentiality have often been referred to as issues of utmost concern in genetic testing contexts.

Access to and use of personal health data is predicated by care providers and scientists on patients' trust in the confidentiality of such data. The entirety of the doctor-patient relationship involves a contract with medical practitioners enforcing strict confidentiality of health-related information. However, third parties are rarely excluded from doctor-patient encounters. Clinic visits are responsibilities of multi-professional teams, including doctors, nurses, physician's assistants, ultrasound specialists, laboratory personnel, administrative staff and hospital controllers. The actual doing of preventative and medical care is dispersed across dispersed health professions, making confidentiality agreements impossible. Unable to act alone, medical data are fragmented amongst health professionals. Therefore, care is proliferated and the continuity of care is compromised.

Control over health data and altruisticism in genetic testing contexts have come a long way from altruistic tissue donation in mono-centric tissue banks. The decade of copyrighting genetic information and attempted 'one-off' commercializations of patents have become embarrassing. Current approaches include re-annotation, community winds of participation, on follow-up commercial use, and sharing royalties. Such practices undermine commercialization, certain areas of the health-care continuum and fields of research, but they energize wider impact and in-depth knowledge of populations through affiliation with multiple and non-IAHAC entities.

1.11 10. Challenges in Implementing Pharmacogenomics

Pharmacogenomic (PGx) testing has become widely available in the past decade and continues to be adopted by many organizations, though formally integrating PGx into clinical practice remains challenging. This article describes the universe of genetic tests available for PGx, quantifies the results of laboratory data reporting PGx information, and discusses best practices for integrating that data directly into clinical workflow. Although health and genetic literacy remain a barrier to implementation, education and easy access to test results are increasingly required so nurses and clinicians can effectively act upon that data. PGx testing is not new, but the number of tests readily available for clinical interpretation has grown exponentially. PGx tests have been commercially available since 2002, accelerated by events such as exploratory FDA black box warnings first published in 2005/2006 and the rising cost of human drug development due to increased complexity and strict regulation, which rapidly expanded into a booming research area for genetic variants with therapeutic implications (C. Nutter & Gálvez-Peralta, 2018). The emergence of next-generation sequencing (NGS) in the early 2010s allowed for the possible evaluation of whole-exome or whole-genome sequencing, surpassing the classical genetic testing of single variants or small panels. PGx tests can be classified using various criteria: test type (mitochondrial, somatic, germline), test method (genotyping, NGS), scope of analysis (targeted analysis, bioinformatic off-target analysis), setting (clinical, nonclinical), and intellectual property (commercial, noncommercial).

PGx testing can provide insights for drug development, marker-based patient stratification, target validation, and postmarketing safety monitoring. Availability of PGx tests for several drugs and associated gene variants has been issued by the FDA. By July 2017, 269 drugs were listed with 371 PGx variants, an increase of 238% and 362%, respectively, compared to 2011. PGx information from reports by diagnostic laboratories can be of value to clinicians and patients by better informing on drug "responders" and "non-responders" along with personalized dose and drug choice recommendation. However, most PGx variants are detected in only one ethnic population, where an even smaller subset of variants is included in corresponding reports, thus limiting global applicability. There remain challenges to accessing these potential clinical benefits: health literacy to consider actioning on tests, genetic literacy, access to reports, time to interpret and act upon reports, assembling resources for actioning on a comprehensive report, and clinical and genetic literacy of these resources or ways of acquiring them. Analysis of 2,341,613 genetic tests performed showed that 207,604 generated PGx reports, indicating that this testing could happen outside licensed laboratories, which presents further challenges regarding health, genetic, and technical literacy actions upon PGx reports.

10.1. Barriers to Education

Despite rapid advancements in the field of pharmacogenomics, there are challenges in adoption within health systems. Current challenges range from lack of formal education to issues with integration into the electronic medical record and the costs associated with the genetic testing (C. Nutter & Gálvez-Peralta, 2018). Pharmacogenomics is defined as the study of interindividual variations in response to drugs due to genetic factors; it aids in determining the dose or choice of a medication based on genetic variations. For example, patients with certain CYP450 variants may be unable to metabolize codeine effectively making it ineffective, or to effectively metabolize clopidogrel making it ineffectively clott inhibiting. Clinically relevant genes included in the panel would include CYP2D6, CYP2C19, SLCO1B1, and VKORC1. Ensuring adequate and timely treatment can be a matter of life or death.

A project for evidencing the impact of education regarding pharmacogenomic testing was conducted. Five goals organized in three phases were determined: 1) To develop an evidence-based pharmacogenomics curriculum appropriate for nurses. 2) To utilize the methods of implementation science to disseminate learning opportunities across local hospitals and the Kentucky nursing workforce. 3) To evaluate the curriculum and learning methods in terms of quality, effectiveness, usage, transfer, and return on investment. For education to be effective, it needs to include knowledge transfer and knowledge utilization. Knowledge transfer is defined as the ability to put learning into action, encompassing the dissemination and use of research findings, as well as the actual adoption of these recommendations. Knowledge utilization is the extent to which a change in knowledge, skills, or attitudes occurs and is applied to practice and evaluation. Post-tests showed a statistically significant improvement in both knowledge transfer and utilization ($p < .0001$). Pharmacogenomic knowledge transfer and utilization increased after education for nurses from both the EdPN and the EMR groups. Statistically significant increases in knowledge utilization were seen for all five utilization questions ($p < .001$ corresponding to a large effect

size). Overall, across Tempe and Piedmont, the EdPN Group was found to have a statistically significant pre- to post-education training change in knowledge transfer ($p < .0001$). Statistically significant increases in knowledge utilization in post-education training was found for all five questions ($p < .001$ corresponding to a medium to large effect size). Further research is needed to assess long-term retention and the impact on patient outcomes. With increasing knowledge transfer and utilization, the examination of patient care outcomes and continued education is imperative.

10.2. Integration into Existing Systems

Patient-specific pharmacogenomic data interpretation allows for selection of medications with the best efficacy or highest safety profile. Application of genetically-informed clinical decision support tools is necessary for change, as there are only modest correlations between providers' genetic scintillation knowledge and appropriate medication selection results. Systems should be adaptable to work with available data points and clinical workflow. With clinical significance, the risk of an ADE for any medication must be considered, but there is currently no adequate model to estimate the ADE risk for a medication when prescribed within pharmacogenomic limitations. Additionally, filtering technologies able to prioritize medications are needed to ensure clinical relevance of the error rate. Recommendations can be presented via a flexible multi-level framework. In interface design, less prominent presentation of algorithm assertions should encourage providers to consider alternative decisions while emphasizing the importance of strictly mandated medications with the highest risk of an ADE (W. Guy et al., 2020). Minimal guidance for safe clinical interpretation of genomic data was available, necessitating the development of guidelines. A new content-based approach for variant interpretation through a modular console application was also developed. Early-stage implementers of genotype-phenotype knowledge bases at academic medical centers should be willing to share lessons learned and challenges faced. In response to the growing pharmacogenomic testing and information and insight into clinician needs, a genetic testing program pilot was developed. Pharmacogenomic testing, clinical resources, training, and patients' electronic health records with reported variants were consolidated to enhance uptake. Barriers to adoption were identified through self-reported surveys and interviews, and strategies to alleviate these barriers based on the transcriptomic medicine infrastructure were addressed. Primary care safety net clinics require additional screening tools for delivering comprehensive presymptomatic genetic testing services. A screening approach is needed to assist providers in disseminating genetic testing and interpretation in primary care settings. Genetic services in this primary care context must be delivered in ways that holders reflect the very nature of effective partnership and patient education.

1.12 **11. Case Studies in Pharmacogenomics**

The following cases present two distinct but common scenarios where the implementation of pharmacogenomic data can produce large effects on patients and their outcomes. Both cases describe an initial scenario without pharmacogenomic lab data or further investigation, as well as a follow-up scenario where pharmacogenomic lab testing and investigation were performed before medication selection and dosing decisions. Both examples utilize widely prescribed medications for which consensus guidelines and decision support tools exist.

Case 1 synopsis: A 52-year old female with depression-like symptoms was started on an SSRI for major depressive disorder. After reporting worsening agitation and insomnia after two weeks of treatment, bupropion was added to mitigate these symptoms. However, after six months, the patient reported no improvement in her symptoms and expressed feelings of hopelessness. Due to the detrimental effect of untreated depression, the patient was referred for further medication management. It was during a treatment evaluation that pharmacogenomic lab data were available.
Case 1 interpretation: The most notable findings from the pharmacogenomic lab report were the recommendations against certain medications. All three medications for which gene-drug interactions were noted belonged to similar drug classes. No alternative strategies were posted in the lab report, requiring the patient to endure a continuation of depression symptoms while a new treatment regimen was established.
Case 2 synopsis: A physician in a busy primary care clinic working with a patient who presented with urinary frequency, urgency, and incontinence prescribed several overactive bladder medications. The dosing and medication regimens were set based on typical dosing for OAB medications. Initial side effect, timing, and symptom follow-up indicated that while the patient's urinary frequency and incontinence were much improved, they still experienced episodes of leaking. After six months, the medication management evolved into a frustrating cycle of adjusting dosing and medication regimens with unsatisfying results, and the medication management was transferred to a different clinician. It was only after review of pharmacogenomic data that treatment options, including dosing adjustments, became apparent.

11.1. Successful Implementation

Multidisciplinary teams at the 1,100-bed Mayo Clinic in Rochester, Minnesota, have created a model to educate health-care professionals in pharmacogenomics (PGx) while translating genetic testing into clinical decision support (CDS) systems. Pharmacogenomics has recently gained attention as a new biomedical field that involves using an individual's DNA to guide a drug/dose selection and monitoring. However, the implementation of PGx still faces multiple technical and clinical challenges, including incorporating genomic lab reports into clinical practice and educating health-care providers. To overcome these challenges, a committee of clinicians, pharmacists, bioinformaticists, laboratory professionals, geneticists, ethicists, and researchers with experience in different areas of PGx research conducted an assessment of the institution's PGx readiness across the eight interconnected components. The evaluation and assessment of the PGx implementation plan continued to iterate even after the laboratory and clinical decision support systems were implemented. The devices and strategies have been created to provide access to information and rules and clinical practice background that allows for better knowledge translation or further learning (J. Caraballo et al., 2017). Clinic encounters that begin with genetic testing are conducted by pharmacists under strict supervision, thus providing clinicians with an opportunity to learn from the interactions they are observing. Chatbots capable of answering dozens of PGx-related queries are developed as part of an educational tool that augments traditional training.
In a more general sense, the use of advanced technologies that can be socially tested and have been evaluated in practice outside the area of genomics, such as Electronic Health Records (EHRs),

may facilitate PGx education and CDS implementation. For example, by using triage systems and minor ailments libraries, clinicians can improve everyday practice through learning while working. On the other hand, complex scenarios like genotype-based therapy recommendations in an emerging but rapidgrowing domain may inhibit essential care practices. Nevertheless, the implementation of Collaborative Educational Support Systems (CESS) is explored as a means to consider both side aspects in a more general sense.

11.2. Lessons Learned

Implementing genetic testing in pharmacotherapy may give greater insight into a patient's drug metabolism and decrease adverse drug events. By integrating pharmacogenomic data into regular clinical practice, a widespread change in prescribing habits could result, utilizing pharmacogenomes as an additional piece of evidence when selecting and adjusting drug therapy. Therefore, obtaining genetic data for multiple drugs is advantageous. The concept of routinely integrated genetic testing into patient care may also be applicable to many teaching hospitals, which presents opportunities for added specialization in the broader field of laboratory medicine. The labs offering pharmacogenomic testing, which administer multiple medications and conditions to screen simultaneously, have considered implementing these tests in a stepwise fashion or in concert with routine testing for traditional laboratory medicine. Education systems need updates to align with new advancements in pharmacogenomics. Creating curricular changes may be difficult, however the challenge is lessened when faculty base plans and intentions on successful past attempts (C. Nutter & Gálvez-Peralta, 2018). Educating nursing students about pharmacogenomics provides the opportunity to teach all nursing students across the state as they receive their education in the same university system. Preparing the educators and faculty may present its own challenges as they will have to learn and be fluent in pharmacogenomics, however as more evidence shows the need for nursing to be on the forefront of personalized medicine, many more exciting opportunities can be created. More options for design than would be available to a stand-alone program are availed with groups of classes being taught at the same time across multiple campuses of a university system and their parent hospitals in a statewide network. It is also natural for the initial pharmacogenomics program to be held in conjunction with the program providing instruction in the fundamentals of population genetics, the next logical course for nursing in the guarantee of personal genetics to be dealt with in further detail.

1.13 12. Future Directions in Pharmacogenomics Education

Pharmacogenomics (PGx) is the study of how a person's genes affect the way they respond to drugs. The goal of PGx is to develop practical tools to enable personalized medicine. A wealth of knowledge on PGx is available, yet translation into clinical practice is inadequate. Pharmacists are medication experts and are increasingly involved in this area as they have an essential role in PGx education and implementation (C. Nutter & Gálvez-Peralta, 2018). Pharmacists have an important role in medication management; ensuring the selection of the correct drug, dose, route, time, formulation, administration, pharmacy preparation, dispensing accuracy, monitoring response, management of adverse reactions, decreased supply costs, recognizes and resolves problems with the medication consumption, and provides evidence-based information on pharmacology and

medicines. A wealth of evidence on the pharmacogenetics of drugs and their clinical implementation is available, but the translation of this data into practice is often inadequate. The profession is facing barriers to implement PGx practices, including the overwhelming amount of PGx information, difficulties in finding reliable and relevant information, health system barriers and limitations in workforce preparedness (W. Guy et al., 2020).

PGx training aimed at health care professionals can mitigate barriers to the implementation of PGx practices. Pharmacists are the most accessible health care professionals trained in pharmacokinetics and pharmacodynamics of medications. PGx is a new, emerging field with no established best practices, and pharmacist training in this area is often insufficient. PGx training for pharmacists varies widely around the world, and hence, a standardized and efficient approach to PGx training for pharmacists is needed. Education of health care providers is essential before any approach to the use of PGx can be broadly implemented successfully, and this process requires a concerted effort on the part of the front line, middle, and optimizing players in the health care system. It is essential to train health care providers in the utility of PGx, as well as the limitations of its current clinical and research application.

1.14 13. Collaboration Between Healthcare Professionals

Everyone needs a little support. In healthcare, everyone stems from a different area of expertise, and these areas of expertise all support positive patient outcomes. Knowledge of pharmacogenomics and how to use pharmacogenomics in practice are essential for healthcare professionals. In order to establish a well-rounded clinical decision support system, collaboration is needed to design education and implement pharmacogenomics to better serve patients' needs (W. Guy et al., 2020). Education regarding pharmacogenomics needs to be broad-based to include many healthcare professionals. This part looks at what the literature suggests about current education programs for nursing, pharmacy, and physician experts.

Pharmacogenomics in Nursing Practice Traditionally, it has been acknowledged that nurses have been overlooked when it comes to learning about genomics and how to utilize genomics in practice (L Norman-Marzella, 2019). Education in genomics is vital for all healthcare professionals, but with focus on nursing, nurses can better incorporate genomics in practice by having a basic understanding of genomics. Education is not enough; nurses need to know when they can apply their knowledge effectively to help patients. With proper education and resources, pharmacists and physicians have been able to implement pharmacogenomics-guided practices. Just as team members in a sporting team work together toward a common goal, nurses are a critical component of the healthcare team, and understanding pharmacogenomics will improve care to better align with patients' needs.

Using Pharmacogenomics in Clinical Practice Today Knowledge of pharmacogenomics is not enough to make a change in practice. If changes are to be made in clinical practice to solve problems, there should be a methodical approach to how change occurs. By examining how pharmacy and physician experts use pharmacogenomics in practice, there could be implications for nurses to use pharmacogenomics to better provide individualized care. Implementing pharmacogenomics effectively into any healthcare practice needs to be considered carefully.

Things to consider are workflow processes, lack of literature tracking the efficacy of application at the point of care, and pharmacogenomics education for individuals who want to confidently use pharmacogenomics. Education programs need to be well-rounded to accommodate the needs of all staff involved.

13.1. Interdisciplinary Approaches

Pharmacogenomics is the study of how genes affect a person's response to drugs. Pharmacogenomics is growing rapidly in importance for clinical care because there are more and more medications with supporting evidence and drug labeling related to pharmacogenomics and patient care (W. Guy et al., 2020). Application of pharmacogenomics and use of data may optimize approach to medication selection and dosing, thereby improving patient outcomes through enhancement of efficacy or reduction of side effects and adverse drug events. There is an increasing body of evidence that supports the use of pharmacogenomics in clinical settings. The FDA has approved testing for genetic variants in several drug-gene pairs where genetic testing may help clinicians make more informed decisions about medication therapy. Genetic testing has the potential to guide clinical decisions on either the selection of alternative drugs or the dosing of the prescribed medications based on stratified pharmacogenomic categories with the accompanying potential for optimizing therapeutic levels. Education in pharmacogenomics from a clinical and laboratory perspective is necessary to ensure efficacy and safety if pharmacogenomics is involved in clinical care. The integration of laboratory testing into clinical decision making is complex, but it is necessary to ensure accurate and consistent application of such testing across the interprofessional team. Education in pharmacogenomics at the undergraduate and graduate levels, as well as continuing education for current professionals, is critical for ensuring safe and effective integration of genomic medicine into everyday clinical practice. In addition, such education should target a wide audience and involve an interdisciplinary approach to ensure that all members of the healthcare team are equally prepared to participate in the use of pharmacogenomics in patient care. This chapter discusses the current state of pharmacogenomics testing related to medication prescribing, focusing on cardiovascular medications, drugs used to treat psychiatric disorders, and medications commonly prescribed by primary care providers, including anticoagulants. Ethical and legal considerations regarding pharmacogenomics testing and application of results are also addressed. For organizations and institutions considering whether to offer pharmacogenomics testing, policies and guidelines to help direct implementation are provided. Challenges regarding educating nurses and implementing pharmacogenomics testing into clinical practice are also explored.

13.2. Role of Pharmacists

The clinical application of pharmacogenomics is advancing rapidly, but there are still questions about how best to integrate it into clinical practice. While nurses and nurse practitioners are valuable contributors to the healthcare team, they are often underrepresented when decisions about pharmacogenomics testing or the use of results to change therapy are discussed. The potential application of pharmacogenomics has been discussed above. Pharmacogenomics could be used in several situations, both reactive and proactive. Pharmacogenomics could be discussed with

patients when patients report a lack of effectiveness or intolerance to a medication or when formulary limitations regarding the use of a traditional agent are discussed. Patients may also indicate interest in pharmacogenomics testing or data. Pharmacists can take an active role in patient education and outreach efforts to discuss the potential use of pharmacogenomic testing or data. Pharmacists may participate in the development of educational programs and information on the potential use of pharmacogenomic testing (W. Guy et al., 2020). Pharmacists can direct patients to institutional or publicly available educational resources to learn more about pharmacogenomics. When pharmacogenomic data are either generated or available and the patient has a previously established therapeutic relationship, pharmacists could take the lead on utilizing the pharmacogenomic data in this therapeutic alliance. Pharmacogenomic data are commonly incorporated into non-oncology medication management workflows. Pharmacogenomic data could be incorporated into medication therapy monitoring plans as applicable or could be discussed through proactive outreach to the patient. From a transdisciplinary standpoint, targeted outreach could be discussed during patient handoffs or care team meetings. All healthcare providers sharing the patient's care would benefit from proactive communication to review how pharmacogenomic data could affect fit and appropriateness of planned medications.

Pharmacists may also take the lead or assist in discussions with providers at institutional review boards, formulary committees, and clinical subcommittee meetings to educate clinicians on the potential value of pharmacogenomic data in a given therapeutic indication. Pharmacists can work with colleagues in clinical informatics to explore how pharmacogenomic data could be integrated into electronic health records systems to further integrate pharmacogenomics into daily clinical practice.

1.15 14. Patient Engagement and Education

Patient engagement and education is essential in pharmacogenomics to improve awareness, understanding, and utilization of testing and results. Educational materials must enhance patient comprehension and attitudes regarding pharmacogenomic information.

A multi-phase study was conducted to develop, test, and deploy three printable and digital patient pharmacogenomics education materials and a supported discussion guide: a general pharmacogenomics booklet, a medication-based booklet, and a multi-gene pharmacogenomics card. Ranging in text complexity between grades 7.5-8.5, materials were focused on pharmacogenomics generally (but not patient-specific test results). A selective survey assessed individual patient or caregiver use of materials. Post-educational interventions assessed both attitudes before, immediately after, and months after a pharmacogenomic counseling session. Study findings could inform future efforts to enhance the development, testing, and use of patient-centered pharmacogenomics education activities on testing platforms (B Asiedu et al., 2020).

Earlier comprehensive surveys identified the need for new or revised pharmacogenomics education and communication materials for patients, guides for providers to assess patient understanding and attitudes, and the need for ongoing education for health care professionals and continually updated materials. Some patient educational materials are available from commercial laboratories, but most of these materials focus primarily on single-gene testing for a single drug.

There are currently no known commercial laboratory educational materials available to explain multi-gene pharmacogenomic testing. A need has also been recognized for materials that would explain how medications are affected by polymorphisms and for educational materials that are general in nature and explain 'what pharmacogenomics is' and its relevance.

14.1. Informational Resources

The agencies below offer a variety of educational resources and materials on pharmacogenomics. For both students and educators, these websites provide curricula and contents for discussion:

1. 2. 3.

Since the development of the first established population pharmacogenomic guidance, clinicians have been able to offer pharmacogenomic testing on a variety of drugs ordered for their patients with the goal of improving safety and effectiveness through prescribing the most appropriate drug and dose. Multiple options are available for obtaining assay information in laboratories. Full-service laboratory pharmacies provide pharmacogenomic assay education and results in easy-to-interpret formats (W. Guy et al., 2020).

Since the 2016 ACCP white paper recommending the integration of pharmacogenomics services into all facets of clinical pharmacy practice, health-system pharmacy organizations have prioritized pharmacogenomics integration into laboratory services, informatics, and clinical pharmacogenomics practice. It is hoped that close collaboration with frontline pharmacists, education and training, and a focus on clinical need, workflow, and ease of use will improve adoption rates.

14.2. Support Groups

A family history of disease is an indicator of potential genetic risk for a child. It can also provide much-needed insight for researchers looking to locate genetic markers for a disease. There is a large amount of data being generated from sequencing efforts, and this data is expensive to analyze and curate genetically validated variants. Even once data are analyzed, it is usually stored in a format incompatible with most analysis and visualization tools. Finally, in a vast majority of cases, without a gene or genetic aberration known to associate with a particular disease, it can be incredibly difficult to determine what filtering path to pursue. As sequencing becomes increasing cheaper and accessible, dealing with raw sequence data will become a bottleneck. Sector 3 focuses on addressing computational needs that will scale with the growing number of individuals sequenced, and it can be broken down into two aims: The first aim is to provide workstations and servers to scientists analyzing sequencing data. Infrastructure will be acquired for on-site analysis and long-term storage of raw and processed genomic data. Technologies will include large hard drives for desktop computers, OS X laptops with high RAM, RAID systems with back-ups of raw sequence data, and servers with fast processors for long-running analysis pipelines. The second aim is to develop visualizations of genotype-to-phenotype relationships and diseases. There are many databases that contain lists of genetic variants associated with a given disease. However, these lists feature little connectivity, and variants are often analyzed independently. One avenue for collaboration could be developing a system that takes a given list and finds other variants occurring in the same genes or pathways (W. Guy et al., 2020).

1.16 15. Regulatory and Policy Framework

The emergence of unique opportunities to implement pharmacogenomics (PGx) knowledge and its clinical applications has prompted the need for proper regulation and policy. The awareness of PGx competency, health disparities associated with non-optimized drug therapy(s), and the advancements in PGx science and technologies have raised the demand for the re-evaluation of current PGx guidelines. Efforts toward regulatory PGx integration advance the biopharmaceutical, clinical, and consumer health industries with respect to drug-target gene unbiasedness, haplotype-wise PGx decision rules, pharmacogenetic test surveillance, and payor reimbursement for PGx applications. The regulatory authority of PGx is being broadened to establish a digital supplement that actively incorporates newly developed PGx biomarkers and drug/biologics. This section discusses how current efforts by various stakeholders may be presented in regulatory and policy frameworks for largescale PGx application (W. Guy et al., 2020).

PGx competency regulations are in demand for non-dispensing healthcare professionals engaged in pre-prescription drug selection and drug response management. Current consensus guidelines on PGx competence that include meta-genotype availability, prescribing interpretation, and patient education of decision support are in concert with advanced research efforts to incorporate PGx training, monitoring, testing, and clinical consultation into formal curricula. To facilitate PGx integration into clinical pharmacy, top-down regulatory efforts are needed to provide dose adjustments of PGx-drug(s) of growing concern accompanied by multi-level PGx competency accreditation for dispensing pharmacists. In the long term, plans for a global P450 empaneling regulation, PGx stewardship, and adherence monitoring are warranted for large-scale PGx applications.

PGx-related disparities in drug therapy and health outcomes are a growing societal concern. Current policies to tackle health disparities caused by non-optimized drug therapy help advance the practice of PGx science and its applications. Key stakeholders are prompted to consider the health burden and economic loss caused by PGx disparities, with plans for consultation groups, PGx testing, capacity building, and PGx education integrated into community healthcare. As the first stakeholders effort toward addressing the growing burden of PGx-related health disparity, it aims to enhance equity in drug therapy for subgroup populations that are genetically resistant to drug treatments.

15.1. Current Regulations

Increasing health care costs, the rise of drug-resistant pathogens, and the continued development of antibiotic resistance threaten the successful treatment of infectious diseases. In response, the FDA has proposed a new mandate for the development of antimicrobial drugs including the provision of pharmacogenomics and pharmacogenomic–clinical applications as part of the Investigational New Drug (IND) package. Clinicians need access to pharmacogenomics information in order to optimize drug selection and doses for individual patients. Major initiatives to make pharmacogenomics information accessible to clinicians include the creation and expansion of publicly available pharmacogenomics knowledge bases like the Pharmacogenomics Knowledge Base, the Clinical Pharmacogenomics Implementation Consortium guidelines

website, and new tools to convert existing clinical reports. The need for pharmacogenomics tools is largely driven by regulations from the FDA and other health care and public safety organizations.

Pharmacogenomics is the study of the relationships between our genetic makeup and how we respond to drugs. The discovery of drug-gene interactions ranging from genetic variations affecting drug target proteins to variants leading to increased or decreased expression of drug metabolizing enzymes has fueled the emergence of the field of pharmacogenomics (HN van Schaik, 2014). However, translating pharmacogenomics knowledge into clinical use has lagged behind discoveries. Investigational drugs in the pharmaceutical industry are clinically evaluated in shallow clinical trials, followed by a multi-year process to gain the regulatory approval of the drug from the FDA. Drug companies need to characterize and assess safety and efficacy profiles to meet regulations from the FDA and other health care authorities. Therefore, the pharmacogenomics actions of newly approved drugs are expected to be provided as part of the New Drug Application (NDA).

15.2. Future Policy Considerations

As pharmacogenomic testing becomes more widely available, clinical practice will need to consider ethical, legal, and policy factors. In addition to concerns about data ownership, privacy, and access, healthcare systems will need to establish best-practices for interpreting and communicating pharmacogenomic test results. Findings may also create new responsibilities for medical providers, such as the obligation to disclose genetic variants with clinical significance that were not anticipated at the time of testing (Rafi et al., 2020). These findings will likely be equally relevant to PGxU as other aspects of the evolving pharmacogenomic landscape.

For pharmacogenomic research, antibody-drug conjugates are a new class of agents that allow for selective targeting of tumor cells expressing a specific receptor. There are currently six antibody-drug conjugates approved for clinical use, three of which target HER2: trastuzumab emtansine, trastuzumab deruxtecan, and fam-trastuzumab deruxtecan-nxki. No clinical factors, including age, have been identified which impair efficacy; however, guidelines recommend caution with the use of these agents in moderate or severe hepatic impairment. Concurrent use of PPIs is contraindicated with trastuzumab emtansine (W. Guy et al., 2020).

Tests measuring trough concentrations of palbociclib or ribociclib may assist with dose selection, specifically in patients considered poor CYP2C19 metabolizers. Tests measuring plasma concentrations of niraparib should be used to adjust the dose for patients with body weight <77 kg or who are poor PMs, following the recommendations in the respective drug labeling. Testing of OATP1B1 genotype will likely become important as paclitaxel-albumin is marketed; however, further clinical studies are warranted before any recommendations are made.

1.17 16. Conclusion

Advancement in pharmacogenomics (PGx) research and evidence leads to the application of pharmacogenomics in government agencies, healthcare organizations, and clinical practice globally. Collaborative efforts of accreditation agencies and professional organizations could mobilize nursing expertise in pharmacogenomics education to enhance the expertise of nurses in

local organizations and community practice (W. Guy et al., 2020). Furthermore, successfully educating nurses in pharmacogenomics could facilitate the comprehensive integration of lab data into clinical practice workflow in healthcare organizations.

Representatives on a flexible base reflecting their constituencies across nursing roles, education, practice, and research are encouraged to lead proactive engagement with those organizations' nursing representatives on boards, councils, and similar tasks forces to ensure nursing perspectives shape the future of PGx. Education-focused, multi-disciplinary grants are pursued, drawing on the expertise of members in founding organizations on grant writing and the extensive evidence courage on education innovation development and evaluation in nursing and across the health professions. There will be a need for consideration of the massive investments in such systems and the complex technical requirements to fully leverage them, but patience and perseverance by nursing leaders and stakeholders is indicated. Time is needed because ground-breaking innovation takes time to be fully realized.

Significantly, a message on the advent of computing, big data, and knowledge at an unprecedented scale will resonate with first-principle thinkers. The churning of knowledge and wisdom at superhuman scales for predictions has been a scourge to society. An equal or greater challenge looms in healthcare with deep data that cannot derive, or even be derived in an understandable manner, quantified care or comprehensible governance. More readable figures of narcotics and arbitrary intervention do not send an uplifting message on PGx and systems biology. Perceptions of unanswered challenges must be transformed into tangible advances for patient care through education and motivation of wide populations in nursing, medicine, pharmacy, and in integrated practice.

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