Executive Summary

Pharmacy and the Future of Precision Medicine (PMI)

Joint Commission of Pharmacy Practitioners (JCPP)

August 1, 2017 Meeting
Hilton, Alexandria Old Town, VA

Pharmacogenomics

The use of pharmacogenomic (PGx) data provides an immense opportunity for pharmacists to improve healthcare through the development of targeted therapies and tools to improve prescribing practices and medication management. The Joint Commission of Pharmacy Practitioners gathered in Alexandria, VA on August 1, 2017 to understand and discuss the landscape, implications, and challenges of pharmacists' role in precision medicine and the use of pharmacogenomics.

Presentation Highlights

Adam Berger, Ph.D. from the Office of In Vitro Diagnostics and Radiological Health from the FDA gave a presentation titled, "Big Picture Overview of Precision Medicine". In his presentation, Dr. Berger highlighted how the practice of medicine is changing to reflect multifactorial influences on health. This was exemplified in his definition of "precision medicine" as an approach to disease treatment and prevention that takes into account individual variability in lifestyle, environment, and genes. His rationale for why tailored healthcare is important to address right now included data advances, better biomedical analysis technologies, established large-scale genome-based research cohorts, more rapid and inexpensive human-genome sequencing, availability of new data, diagnostic, and sensor data, and the public becoming more involved in clinical care and research. Dr. Berger highlighted the many participants within the areas of science, standards and access, and translation and regulation were all working towards the PMI mission:

"*To enable a new era of medicine through research and technology that empowers patients, researchers, and providers to work together toward development of individualized therapy*."

Dr. Berger emphasized how the success of personalized medicine depends on having accurate, reproducible and clinically useful companion diagnostic tests to identify patients who can benefit from targeted therapy. Other factors he described include having a learning health system that encourages researchers and clinicians to learn from the patient experience, to develop targeted treatments that are more effective or less harmful for specific individuals, and to update research and regulatory policies that support development and assure quality. These policies may center around implementing adaptive standards and supporting database development with evidence for clinically relevant genetic variations. In terms of public engagement, Dr. Berger stressed the need for clarity and transparency about testing performance and limitation, incentivizing data sharing, common nomenclature for standards and test results, and developing more reference materials. He stated that after results are returned, ethics,

education, interprofessional training, community resources, database evidence, and implications are all areas for further consideration.

Julie Johnson, PharmD from the University of Florida - College of Pharmacy gave a presentation titled, "Pharmacy and the Future of Precision Medicine". In her presentation, Dr. Johnson provided an overview of the potential pharmacogenetics could have on clinical practice. She gave a brief history of pharmacogenetics and then focused on what the University of Florida has been doing the last 3-5 years within this field. These activities include being an Implementing Genomics in Practice Networks (IGNITE) site and many educational efforts through student pharmacy coursework, experiential learning, post-PharmD training, certificates, and conference offerings.

Dr. Johnson emphasized the need to rely on Clinical Pharmacogenetics Implementation Consortium (CPIC) guidelines for clinically-relevant examples and to be cautious of how some commercial firms are making recommendations based on little evidence. She also stated an area of improvement is understanding how panel-based testing is stored in electronic health records (EHR) and the need for pharmacists to have full access to this information. Once large scale genomic information is available to patients the focus will not be so much on the pharmacogenetic tests, but rather on how and when the data should be used.

Moreover, costs of panel-based testing must be better understood because at this time most payers do not cover panel-based testing. Pharmacogenomic information is being looked at more in Accountable Care Organizations (ACO) models as an opportunity to reduce cost on the back end. CPIC guidelines are funded by the National Institute of Health (NIH), but other methods of attaining revenue must be explored if funding is not continued.

Pharmacy Practice Panel

Sam Johnson, PharmD facilitated a pharmacy practice panel consisting of Theresa Tolle, BPharm representing community practice, James Hoffman, PharmD representing hospital/institutional practice, and Sandra Leal, PharmD representing population-based practice. Each panelist described what they did, how they did it, for what population, and how they addressed coverage and other administrative issues.

Pharmacist Toll described how Bay Street Pharmacy became involved with interpreting pharmacogenomic testing. She advocated for more education for pharmacists to understand the testing process and the application of results. She also advocated for the need for legal requirements that addressed test payments, pharmacist services payments, and kickback laws. The Bay Street Pharmacy was able to recruit patients through direct marketing to physicians, recommending tests based on individual patient profiles, community group presentations, publishing articles, and in-store marketing. She then described the typical pharmacogenomic patient process and ongoing barriers.

Dr. Hoffman discussed the PG4KDS clinical implementation model at St. Jude Children's Research Hospital. The goal of this program is to migrate assay-based pharmacogenetic tests from the laboratory into routine patient care for preemptive use. This model blends inpatient and outpatient practice settings and focuses on the pharmacist as the individual responsible for implementing pharmacogenetics. Dr.

Hoffman also described health systems with greater than or equal to one full-time employee dedicated to pharmacogenetics and the purpose of the Clinical Pharmacogenetics Implementation Consortium (CPIC) and key assumptions this consortium makes. He emphasized how CPIC guidelines are designed to help clinicians understand how genetic results should be used rather than if tests should be ordered.

Dr. Leal explained how pharmacogenomics is integrated into SinfoniaRx's personalized Medication Therapy Management (MTM) program at their Integrated Behavioral Health site. Their research at SinfoniaRx involves implementation strategies, focus groups with providers and patients, analyzing result trends and outcomes, and investigating reimbursement. Dr. Leal thought it was important to consider who the vendors are, who houses the data, what is covered by insurance, whether it should be the whole panel or just some genes, as well as how interoperability will operate in the future. She also addressed the needs of electronic health records and the need to store genetic information as structured data.

Concurrent Discussions on Problems and Solutions

EDUCATION

James Hoffman facilitated the discussion on issues related to education and continuing professional development. The goal of this session was to determine what education needs for students and practitioners in the area of personalized medicine and pharmacogenomics needed to be considered by JCPP organizations. The key challenges and solutions can be summarized in the following table:

Challenge/Opportunity	Solution/Approach
In student education, there is an opportunity to: 1. To create and evaluate standards better 2. Create experts in personalized medicine 3. Increase resources for teaching a. Not enough practice sites 4. Challenge students more 5. Train interdisciplinarily with other professions which may have limited training as well	Approaches to these opportunities are to: 1. Map out how course information matches to ACPE standards 2. Tailor educational needs at schools by offering a scale of options depending on the available clinicians/experts. 3. Educate students about what resources are available and where a. Create more IPPEs/APPEs that include PGx 4. Encourage life-long learners that extend beyond school 5. Engage with the interdisciplinary professional education council (IPEC) and accreditors to coordinate education or to provide a universal online genomics course
In preceptor education, there is an opportunity address the same issues students have.	These opportunities can be approached by creating certificate programs, which may address certain needs through remote education.

In practitioner education, there is an opportunity to: 1. Assist with implementing pharmacogenomics and engaging other providers 2. Ensure pharmacogenomic information is curated 3. To avoid over-regulation by the government	Approaches to these opportunities are to: 1. Create aids for clinical decision making 2. Make the work of CPIC more visible and sustainable and have pharmacists maintain role of curator at practice site 3. Ensure the profession leads the way a. The FDA may have an interest in supplanting NIH

Other considerations regarding education needs are:

- Clinicians should teach courses to show how pharmacogenomic data is relevant in practice
- One elective course will not meet the PGx competency needs
- AACP has a special interest group where resources could be incorporated in PharmD education
- There are educational materials on PharmGKB and the 2017 White Paper Genomic Literacy Education
- The discussion around the level of education and knowledge is not a static question, but something that likely will need to be addressed over a broader timeline, for example, pharmacokinetics about 30 years ago
- Whether entrustable professional activities related to pharmacogenomic services exist and may serve as an alternative to an education requirement

PRACTICE & DEVELOPMENT

Theresa Tolle facilitated the discussion on issues relating to practice and development. The main goal of this session was to determine what practice and coverage considerations are needed to integrate personalized medicine and pharmacogenomics into pharmacy practice.

Challenge/Opportunity	Solution/Approach
In the pharmacist's role and scope of services the pharmacist provides, there is an opportunity to: 1. To understand the collective data available to show the impact or value of PGx services provided by pharmacists	Approaches to these opportunities are to: 1. To recognize why pharmacists are best to provide these services: a. Pharmacists are accessible to directly answer patient questions b. Pharmacists are able to optimize therapy, increase care value, improve professional fulfillment, reduce readmissions, reduce medical expenses by interpreting tests to help patients understand how pharmacogenomics correlates with medication and lifestyle. c. The pharmacist plus a test is better than the test alone

In order to optimize the use of pharmacogenomics within the pharmacist patient care process, there is an opportunity to: 1. Have proactive discussions about pharmacogenomics and to create standards that outline the use of pharmacogenomic data 2. Share data across different healthcare settings 3. Remove blocks that some pharmacy benefit managers place on access to pharmacists	Approaches to these opportunities are to: 1. Develop adaptive standards around the proactive usage of PGx data. 2. Fully integrate pharmacogenomic data into electronic health records, communicate with pharmacy management software, and to enhance decision support systems 3. Handle pharmacogenomic information like any other health information
In relation to reimbursements for tests and related services, there is an opportunity to: 1. Create partnerships with companies, determine the regional coverage of Medicare 2. Consider reducing "drug cost" vs "medical spend" 3. Avoid PBM management of pharmacogenomic services 4. Increase the number of payment models for data interpretation, or the services related to the test, rather than the test itself	Approaches to these opportunities are to: 1. Identify who the potential payers are and why they would pay for services 2. Create a distinction between "drug cost" and "medical spend" 3. Determine pharmacogenomic counseling as a paid MTM service 4. Advocate for separate coverage for tests and pharmacists services related to test

Other considerations to make in practice and development are:

- Standards should exist for the labs/companies who create the tests
- Manufacturers should share preclinical data to inform practitioners how pharmacogenomic data may impact treatment
- More research that publishes pharmacists using pharmacogenomic data and tests may help fill knowledge gaps

PRACTICE & DEVELOPMENT

Sam Johnson facilitated the discussion on issues relating to policy and regulation. The main goal of this discussion was to determine what policies and issues needed to be addressed by pharmacists and the JCPP organizations. Some of the items that were discussed in this section were addressed in the education and practice discussions, respectively, and will not be reiterated in this section.

In order to address whether a pharmacist can independently order a test or whether a referral by another provider is necessary, these themes were accentuated:

- Authority - whether pharmacists perform tests independently or with approval from the FDA
- Specific tests - diagnostic versus therapeutic, specific gene versus genome
- Terminology - "germline" versus "genetic" and "pharmacogenomics" versus "pharmacogenetics"
- State-by-state variation
- Provider status - the ability to order tests is affected
- Timeliness - whether testing should be routine, what happens when there is no response to test or response is not in a timely manner

Data related to privacy was also a key area that was addressed:

- The value of data is aggregate, but privacy is an issue
    - Who owns the data and what permissions are given?
    - Patient privacy - patients want ownership over their data
        - May be information payers want, but patients are uncomfortable sharing

- How much data is going to be sold for?
- What is going to be done with data?
- How can data be shared?

In terms of pharmacist collaborations with other healthcare professionals, there is a need for communication to ensure that efforts are not being duplicated. An approach may be to look at current models where interprofessional collaborations are being used and then defining what each individual is doing in each of these models. The scalability of these models could then be considered. For pharmacists to collaborate interprofessionally, this necessitates a defined pharmacists' scope of practice and the level of counseling provided. An approach that was suggested for addressing scope would be to define "minimal risk" versus "more than minimal risk"; pharmacists could provide counseling for minimal risk.

Other considerations to make in policy and regulation related to pharmacogenomics are:

- There are variations in clinical lab fee schedules
- The cost of tests depends on the type of test and individual patient coverage
- The advocacy message may be that pharmacogenetics should be used as an additional tool
- The value of pharmacists using pharmacogenomic data must be highlighted

Conclusion

By addressing challenges in the areas of practice, education, policy, and regulation, each JCPP organization was able to enhance knowledge of the implications pharmacogenomics has on their organization's membershipm the profession and on patient care delivery. The potential approaches determined during the concurrent discussions provided a framework to strengthen organizations' abilities to assist in the provision of pharmacogenomic data and its use in the provision of pharmacist-provided patient care and the field of precision medicine.