Advancing Pharmacogenomics in Pharmacy Practice

The American Pharmacists Association (APhA) Foundation invited a group of inter-disciplinary stakeholders to be part of the Committee to Advance Pharmacogenomics in Pharmacy Practice to discuss the role of pharmacists in personalized medicine. The committee convened on November 7-8, 2012, in Washington, DC with participants representing academia, pharmacy association, national chain pharmacy, health systems, research institute, and consultant pharmacy. The goal of the committee meeting was to gather information that would outline a strategic plan to advance pharmacists' patient care services in pharmacogenomics. Key areas of discussion included the science of pharmacogenomics and its application to current practice, consumer genetic testing, patient safety, efficacy, clinical outcomes, pharmacogenomic counseling, patient privacy, confidentiality, ethics, treatment algorithms, practice models, data collection and management.

Through unique insight from participants, a thematic structure for a strategic plan to advance the translation and application of the science of pharmacogenomics in pharmacy practice was generated. To enhance the strategic plan outline, the recommendations of this committee have been integrated with suggestions from the 2009 Whitepaper report from the American Pharmacists Association titled Integrating Pharmacogenomics into Pharmacy Practice via Medication Therapy Management. This white paper synthesized information from the Department of Health & Human Services Personalized Health Care Initiative, the Food and Drug Administration pharmacogenomics activity, and the Utilizing e-Prescribing Technologies to Integrate Pharmacogenomics into Prescribing and Dispensing Practices Stakeholder Workshop. The strategic plan included herein is intended to guide pharmacists, other providers, patients, payers, policy-makers, and the public in efforts to implement and promulgate pharmacist-provided pharmacogenomic services.

Research/Evidence

- **Objective:** Conduct demonstration projects to evaluate practice models for pharmacist-provided pharmacogenomic services
    - **Task:** Perform an environmental scan to identify potential research collaborators, including those who can provide resources or financial support
        - **Potential Partner/Resource:** Regulators/standards development and commercial genetics organizations may be interested in evaluating results of demonstration projects in order to design and refine standards
    - **Task:** Design and conduct projects to evaluate the care model and prove the value pharmacists can have on the "high impact" drug/genomic or disease state/genomic areas
        - **Tactic:** *Payers* identify readily available opportunities for pharmacogenomics applications that can improve patient outcomes and reduce total costs for care over time.
        - **Tactic:** *Research and development organizations* develop studies to answer the question of how clinicians should best utilize pharmacogenomic information to improve the lives of their patients.
            - **Potential Partner/Resource:** Well documented and clinically relevant therapeutic opportunities in CYP2C19, CYP2D6, and CYP3A4 metabolism classes.
    - **Task:** Identify and test potential payment models for pharmacists' pharmacogenomic services
        - **Tactic:** *Payers* participate in demonstration projects that conduct return-on-investment analysis, including credible third-party cost-effectiveness analysis for pharmacogenomic tests/drugs.
            - **Potential Partner/Resource:** ACOs, health economists
- **Objective:** Translate the outcomes of pharmacogenomic demonstration projects into resources for pharmacy practice
    - **Task:** *Research and development organizations* collaborate with practitioners and pharmacogenomic tool-developers to determine the focus of resource creation (e.g. What resources will be most helpful for empowering pharmacists to provide pharmacogenomic services?)
    - **Task:** *Research and development organizations* create better clinical diagnostic support tools and develop a method to capture genomic information relevant to each drug and related to drug–drug interactions.

Practice or Business Models, Standards and Policies

- **Objective:** Create standards for securing, reporting, and sharing pharmacogenomic data
    - **Task:** Identify best practices and standards for appropriate use of data.
        - **Tactic:** *Practitioners* identify what pharmacogenomic data are needed to make relevant clinical decisions, who should have access to the information, and what level of detail should be shared among providers.
        - **Tactic:** *Facilities* integrate pharmacy point-of-care genetic testing, ensuring that data are readily retrievable and easily shared.
        - **Tactic:** *Payers* remove themselves from the clinical decision process.
    - **Task:** *Regulators/standards development organizations should* harmonize standards, terminologies, and their uses.
- **Objective:** Create an implementation plan for widespread adoption of proven pharmacist-provided pharmacogenomic services.
    - **Task:** Bring together a planning and oversight committee to drive plan creation and adoption
        - **Tactic:** Bring together committee members who will be the key implementers of the developed plan
        - **Tactic:** Continuously engage multidisciplinary leaders to monitor the progress of the plan
            - **Potential Partner/Resource:** National chain pharmacies, networks of community pharmacies
            - **Potential Partner/Resource:** Investors; venture capital firms, health plans, insurers and other payers
            - **Potential Partner/Resource:** Multidisciplinary representation from groups who will be interacting in implementation or have experience in pharmacogenomic or genomic service delivery
    - **Task:** Aggregate best practices into a standardized pharmacogenomic patient care model
        - **Tactic:** Providers should actively engage in and adopt interprofessional practices that create and utilize highly accessible and pharmacist-provided pharmacogenomic services.
        - **Tactic:** Pharmacists maintain strong, trusting and mutually beneficial relationships with patients, physicians, other providers and encourage those individuals to promote pharmacists' patient care services.
        - **Tactic:** *Regulators/standards development organizations* encourage and support professional organizations in developing appropriate guidelines and requirements for pharmacist-provided pharmacogenomic services.
        - **Tactic:** *Regulators/standards development organizations* develop point-of-care testing guidelines/protocols/standards.
    - **Task:** Create, adapt, or endorse treatment algorithms with specific inputs to yield meaningful and valuable outputs

        - **Tactic:** *Practitioners* clarify pharmacist, physician, and other providers' roles related to interpreting and applying genetic test data to medication management
        - **Tactic:** *Regulators/standards development organizations* expand drug labeling and make pharmacogenomics information readily available to aid in the application of treatment algorithms.
        - **Tactic:** Create a Genomic Scholars Consortium that would review current information and develop a Genomics Handbook (like Handbook of Non-Prescription Drugs) that provides an overview of all genomic tests and recommendations.
            - **Potential Partner/Resource:** HRSA
            - **Potential Partner/Resource:** Coriell Institute for Medical Research
            - **Potential Partner/Resource:** Genomic test providers (potential funders)
            - **Potential Partner/Resource:** Pharmacy Library (or other online platform) for Genomics Handbook so information is up-to-date
    - **Task:** Prepare systems and facilities to offer pharmacogenomic services
        - **Tactic:** Health systems create and expand an infrastructure that embeds pharmacists' patient care services and collaborative practice agreements into care.
        - **Tactic:** *Facilities* adopt guidelines, policies, and procedures related to privacy, confidentiality, and ethics.
        - **Tactic:** *Facilities* implement policies that align system gains with individual practitioner efforts.
        - **Tactic:** Incorporate standards into Pharmacy Practice Accreditation Standards for the hospital and community when appropriate.
        - **Tactic:** *Education organizations* integrate pharmacogenomics into community-based public health programs.
    - **Task:** Develop payment mechanisms for pharmacists' pharmacogenomic services
        - **Tactic:** *Payers* align financial/reimbursement incentives/disincentives for adoption.
        - **Tactic:** *Payers* offer team/outcome-based payment reform rather than a "silo-based" provider payment model.

Education

- **Objective:** Embed pharmacogenomic education into the pharmacy curriculum to create a long term solution for increasing pharmacists' baseline knowledge
    - **Task:** Develop timely educational materials be taught in the classroom and assure content is up-to-date and readily accessible across schools and colleges
        - **Potential Partner/Resource:** NHGRI G2C2 curriculum competencies – exemplar for school trying to implement, may provide opportunity for IPE
        - **Potential Partner/Resource:** General IPE competencies can be applied to pharmacogenomics
        - **Potential Partner/Resource:** ACPE & AACP will need to be in the conversations
        - **Potential Partner/Resource:** EDx – teach courses in many schools
    - **Task:** *Education organizations* disseminate lessons learned, barriers, and successes related to teaching pharmacogenomics.
        - **Potential Partner/Resource:** HRSA
    - **Task:** *Education organizations* integrate pharmacogenomics into clinical and didactic education throughout curricula (e.g., PharmD, MD, DO, RN), including interprofessional training and practice models at the degree, residency, fellowship, and specialty certification levels.
        - **Tactic:** *Education organizations* encourage innovative practice models that use genomic information in clinical decision making
- **Objective:** Create continuing education programs to update practitioners on the science and practice of pharmacogenomics.
    - **Task:** Compile education resources for pharmacists to build and maintain their pharmacogenomic knowledge, including implementation and documentation education and cultural competency for specific genomic issues.
        - **Potential Partner/Resource:** G2C2 from NHGRI
        - **Potential Partner/Resource:** APhA Certificate Training Program and case-based education
        - **Potential Partner/Resource:** National Library of Medicine's Wendy Rubenstein can provide input on which genomic tests are credible
        - **Potential Partner/Resource:** CDC news feed on pharmacogenomics
        - **Potential Partner/Resource:** Coriell Institute for Medical Research Pharmacogenomics Advisory Group which meets twice yearly to review, discuss and validate the importance of various drug/gene combinations
    - **Task:** Encourage and empower pharmacists to become teachers of pharmacogenomics.
        - **Tactic:** Create a train-the-trainer program to help pharmacists gain the clinical and practical skills required to become champions of pharmacogenomics in their communities.
            - **Potential Partner/Resource:** ASHP Emerging practice areas
            - **Potential Partner/Resource:** APhA e-Communities

Health Information Technology

- **Objective:** Develop HIT infrastructure that supports data management, data sharing, and ethical use standards
    - **Task:** *Regulators/standards development organizations* request pharmacists' input during EHR standards development.
    - **Task:** *Vendors* deliver integration, interoperability, and seamless incorporation into practices/facility workflow.
        - **Tactic:** *Vendors* build pharmacogenomic decision tools into software packages.
        - **Tactic:** *Vendors* comply with HITSP (Health Information Technology Standards Panel) and other relevant standards and participate fully in the interoperability development process.
        - **Tactic:** Develop and adapt standard classification system to minimize system-to-system variability in the data reported (e.g. classification and language).
- **Objective:** Advocate for pharmacists to be at the table to ensure that information flows into pharmacies and there are capabilities to capture information in the pharmacy (including pharmacogenomics)
    - **Task:** *Practitioners* convey the need for secure electronic transmission of genetic/pharmacogenomic data to HIT vendors.
        - **Potential Partner/Resource:** Registries for drug/genes (biobank)
        - **Potential Partner/Resource:** Pharmaceutical companies' biobanks
        - **Potential Partner/Resource:** PharmGKB
        - **Potential Partner/Resource:** eHIT Collaborative
    - **Task:** *Practitioners* work with HIT vendors to standardize the transmission of genetic and pharmacogenomic data.
    - **Task:** *Vendors* enable the secure electronic transmission of genetic/pharmacogenomics data to/from pharmacy practices.
    - **Task:** *Vendors* publish industry guidelines for facility and practitioner requirements for use of professional tools.
- **Objective:** Develop repositories for pharmacogenomic information and a uniform way of communicating it from drug databases and systems (clinical decision support/dispensing systems in pharmacy practices).
    - **Task:** *Facilities* update software/hardware to support data exchange, including using broadband to enable better information exchange among health care workers and patients.
        - **Potential Partner/Resource:** ASAP
        - **Potential Partner/Resource:** ScriptPro
    - **Task:** Develop the ability to generate pharmacogenomic reports from HIT in a standardized/meaningful way that will be useful for patients and providers.

Awareness/Advocacy

- **Objective:** Publicize the importance of pharmacogenomics to pharmacists to generate awareness of the role pharmacists can play
    - **Task:** Develop vignettes that create the value statement about pharmacists' impact through pharmacogenomics and how to get involved in the field
        - **Potential Partner/Resource:** "Just the Facts" on APhA website (e.g., marijuana and warfarin – attention grabbing stories to get pharmacists engaged)
        - **Potential Partner/Resource:** CPIC guideline development – getting pharmacists at the table
    - **Task:** Create Special Interest Groups or mentor networks of current practitioners who are in the field to help others break through barriers.
- **Objective:** Create awareness in the general public through marketing/PR that highlights the pharmacist's role and personalized medicine in an effort to change patient expectations
    - **Task:** *Patients/consumers* obtain a baseline level of understanding of pharmacogenomics.
    - **Task:** *Patients/consumers* appreciate the benefits of pharmacogenomics.
        - **Potential Partner/Resource:** Family history (NIH tool)
    - **Task:** *Patients/consumers* become informed about, understand, and engage in an informed understanding of privacy/security risks and protections.
        - **Tactic:** *Patients* receive additional education/counseling about what is available from health care providers.
        - **Tactic:** *Patients/consumers* discover mechanisms for patients to order valid tests directly from labs.
- **Objective:** Advocate for the pharmacists' role to national and local legislators, policymakers, and payers/decision makers (e.g. pharmacists' ability to order drug-related lab tests)
    - **Task:** *Regulators/standards development organizations* empower the clinical use of pharmacogenomics.
        - **Potential Partner/Resource:** National pharmacy organizations

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