

Environmental Scan of Pharmacogenomics in Health Care HIT Infrastructure

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Pharmacy Health Information
Technology Collaborative



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1. SUMMARY

Pharmacogenomics (PGx) is a fast growing part of patient care. As the role of pharmacists in patient care continues evolving, pharmacists are uniquely positioned to lead PGx integration into clinical pharmacy practice, particularly with regard to drug selection and PGx testing, though this will not be without challenges. With this in mind, the Pharmacy Health Information Technology (PHIT) Collaborative embarked on a project that culminated in the release of its first [*Environmental Scan of Pharmacogenomics Coding: Current Practice and Barriers*](#) in June 2015.

Environmental scanning is a vital process for decision-making and planning. It is a systematic approach that allows leaders of organizations, businesses, professions, etc., to survey and monitor their environments; looking at the sources and factors that influence the landscape in which they operate, including their potential impact on practices, services, and operations. The process includes reviewing available literature on specific topics; examining case studies; looking at legal, regulatory, economic, socio-cultural, ecological, and technological factors; and providing interpretation and analyses of the information collected as to their relationship to the internal and external environments examined.

In the five years since the release of PHIT's first environmental scan, advances in PGx implementation and testing have been realized. With these advances also come new potential barriers and challenges for pharmacists that need to be researched, examined, and discussed. So that pharmacists can continue playing an invaluable role in this growing field, the Collaborative revised and updated the 2015 environmental scan document to capture some of these advances.

Among the key areas this updated document looks further into include:

- use of PGx in health care;
- electronic infrastructure necessary for exchanging PGx data and test results;
- interoperability of electronic health records (EHR);
- potential policy and regulatory issues;
- case studies, and
- workflow processes.

As the needs of health care continue to change and the demand for health care services increases, pharmacists will be among the health care providers adapting and creating innovative patient care and new pharmacy services. Pharmacists will provide a critical link between PGx and the patients they serve. Environmental scanning will aid pharmacists in their decision-making.

2. Overview

PGx continues to play a growing role and an important part of patient care. PGx combines pharmacology and genomics to study how genes affect a person's response to drugs.¹ PGx information allows pharmacists and other health care practitioners to identify which patients may respond to specific treatments or predict which may have increased toxicity, or poor efficacy, while optimizing drug efficacy and minimizing morbidity and mortality.

Pharmacogenetics (PGt) is a term often interchanged with PGx; however, they are distinguishable



terms. From a regulatory perspective, the International Council on Harmonisation (ICH) defines PGt (a subset of PGx) as the study of variations in DNA sequence as related to drug response.² Alternatively, ICH defines pharmacogenomics as the study of variations of DNA and RNA characteristics as related to drug response.³

In order to effectively use a patient's genomic information, methods must be developed to incorporate it into the electronic health record (EHR) to assist with therapeutic decision-making. Information related to PGx, including patient-specific information, should be easily accessible to health care practitioners, including pharmacists, when evaluating appropriateness and safety of new drug therapy from diagnosis.

The value of PGx testing continues to be of significant debate due to limited economic evaluation studies that could better inform policymakers considering research and development and coverage and reimbursement of tests and related services.⁴ Widespread efforts are under way, determining which PGx biomarkers are actionable and may result in clinically meaningful outcomes. More than 280 medications include PGx information in their package labeling information.⁵ The labeling information includes genes that influence drug exposure and clinical response variability, risk for adverse events, genotype-specific dosing, mechanism of drug action, polymorphic drug target, and disposition genes. The speed of the discovery of genetic biomarkers far outpaces the understanding of corresponding clinical significance, as well as the incorporation of this data into current clinical practice.^{1,2,4}

PGx testing is also becoming more affordable as in-home testing gains popularity. These tests provide information on a portion of the genome. They use genotyping to look at specific portions of the DNA, including sections that affect medication response.⁶

As genomic information becomes more prevalent, standards are necessary to facilitate communication among different sectors of the industry and promote best practices. The Health Level Seven International (HL7) [Clinical Genomics Work Group](#) supports precision medicine by working within and outside of the HL7 community to develop and promote shared standards for the meaningful exchange of genomic and other information at clinical, personal, and population levels.

To maximize the benefits of PGx, many different issues need to be taken into account. The following discussion looks at several of these important topics, which should be considered when working to move PGx forward. These topics include: policy and regulatory issues, payment structure, provider roles and competencies, practice models and workflows, and informatics issues.

3. Discussion

PGX PRACTICE MODELS

Currently, because of the high cost of PGx testing, not everyone can be selected for testing and lack of insurance coverage. Capturing PGx data in a usable form for pharmacists to document potential health concerns, adverse drug reactions, and disease specific prescribing are important and needed for improving future technology solutions. Identifying PGx potential workflows will enable the ability to review gaps and recommend needed codes.



OVERVIEW OF GENOMICS TESTING AND HOW IT RELATES TO PGx TESTING

Just as genomics testing can help predict the possibility of developing certain disease states, PGx testing can help predict how patients may respond to drug therapy. PGx testing can help predict the degree of clinical response to a drug or whether a drug may cause toxicities or adverse drug reactions based on how the patient is genetically predispositioned to metabolize that specific drug.

Workflows for PGx will evolve as the science moves more from testing to testing interpretation, education, and clinical use. The scope and potential of PGx results reaches far beyond just lab results to physician information transfer. These results provided to physicians or other providers can assist in guiding therapy.

Ordering laboratory tests may originate from a provider, pharmacist, or directly from the patient/consumer. Test results may be accessible to providers and patients from an online cloud, mailed to the ordering source, or may interface with the EHR. PGx test results are not likely to change like other health indicators or clinical values.⁷ Metabolizing status for particular genes could be listed as an allergy intolerance, potential intolerance, or potential ineffective medication. Results would then either be used by the provider to guide therapy directly or evaluation and interpretation could be performed by a pharmacist and recommendations made to the treating provider by the pharmacist for implementation in the patient's care.

Many laboratories perform PGx testing alone. However, others may add PGx to tests they already perform.

Education and counseling to providers and patients are important because different gene testing has differing levels of evidence, and the level of evidence to provider result in laboratory test reports varies from laboratory to laboratory.⁸ How testing is done may not be divulged by the laboratory because it is proprietary, though there may be differences in laboratory test results depending on what single nucleotide polymorphisms (SNPs) are tested for and whether the laboratory depends on sequencing or utilization of SNPs for their reported results. Level of evidence is also important for specific gene-drug metabolism because clinical interpretation may be tempered as a result of this level of evidence and the amount and quality of research utilized to arrive at a testing result.

PGx can help avoid medication-related problems (MRPs) and lower health care costs by assisting in the adjustment of current medication therapy through product selection or dose adjustment, guiding future therapies by knowing how an individual metabolizes medications, or enabling clinicians to look for etiologies of past medication intolerances or therapy failures. By utilizing PGx, much of the therapeutic guessing for optimal therapies and possible serious adverse drug reactions (ADRs) can be avoided. This presents the opportunity to increase the quality of patient care while decreasing health care costs.⁹

Access to PGx services so far has been limited by lack of insurance coverage, expense of the testing, lack of public awareness, inability to recognize clinical relevance, and a lack of clear, decisive actions the health care provider should take in order to mitigate genomic interactions with medications.¹⁰ Insurance now pays for specific testing regarding serious drug-gene interactions, such as abacavir skin reactions, but may be slower to pay for other less defined, less serious drug-gene interactions. The expense for testing is trending down, however, and more genes are becoming available to test while public awareness is increasing from direct-to-consumer marketing from some companies.

The process usually begins with a physician order to the laboratory after consent from the patient; however, a pharmacist within their scope of practice could order a test now and in the future.



Results are obtained, reports are generated, and are either mailed directly to the patient or made available to the ordering clinician. The report then can be interpreted by a physician, pharmacist, or other knowledgeable health care professional. However, if laboratory reports were sent directly to patients, the patients would need to seek out a health care professional to read and interpret the reports.

Logistical issues are noted in some locations with regard to PGx services workflow turnaround time for laboratory results and then reporting test results to the patient after the laboratory report is generated. There can be one week to as many as three to four weeks for laboratory test processing and report generating time, so workflow to see the patient after the results are received and report generated must take into account patient accessibility at some point in the future.¹¹ Clinical Laboratory Improvement Amendments (CLIA) certified laboratories would be the preferred laboratory to utilize for quality purposes. Improvements in turnaround times of laboratory results are occurring as a result of the interoperability of health IT systems.

All practice settings

PGx testing results in an increased complexity of service in all practice settings. As such, implementation into practice requires adaptation of existing processes to allow for a dedicated interaction with a patient that includes significant review of the test results, implications for prescribed therapies, and education of the patient about communication regarding future therapies. Use of the Pharmacists' Patient Care Process and a dedicated consultation room or privacy area is highly recommended for successful PGx testing and counseling.¹²

Ambulatory

PGx testing lends itself well to the pharmacist ambulatory setting because of the large and growing number of genes that can be tested across disease states and more time can be devoted to explanation of the metabolism of medications to treat many of those diseases. Pharmacists in this setting often have access to a health-system EHR and can leverage processes and protocols to modify or make recommendations to change medication selection, medication dose, avoid documented intolerances, and minimize ADRs. This setting allows for laboratory results interpretation, in-depth education, and application of results to current and future medication therapy possibly in the context of a pharmacotherapy consult.

Community

Application of PGx testing and counseling in the community pharmacy setting requires significant modification of the traditional fee-for-service model currently used. PGx services can be implemented more quickly and completely if EHR access is available while PGx clinical services are performed. There may be limited or nonexistent access to other laboratory results, and this limited access to a patient's EHR may present a barrier to a holistic view of the patient. Technology, such as eCare plans, is closing that gap through improved interoperability and sharing of data. Community pharmacies with staff trained and dedicated to advanced patient counseling, clinical services, point-of-care testing services, and thorough coordination of care with other health care providers may successfully implement a full suite of PGx services. CLIA certification or waivers are needed.

Inpatient

A concern with inpatient PGx laboratory results is that testing may have already been done at the outpatient setting and the results were made available to those providing the outpatient PGx services. Applying those outpatient testing results in an acute care facility may not be reasonable because of the long laboratory reporting turnaround time and interoperability issues. Services could



be utilized if a patient has PGx test results and can have them scanned into the EHR. Staff training to interpret and apply test results may be required. In time, turnaround times will likely improve, as well as the number of genes that may be tested for locally.

CASE STUDIES

The previous Pharmacy HIT Collaborative's [*Environmental Scan of Pharmacogenomics Coding: Current Practice and Barriers, June 1, 2015*](#), has examples of entities utilizing PGx information in their practices and how they incorporated this information into the electronic health record.¹³ Updated examples from Tabula Rasa HealthCare and Vanderbilt University Medical Center from PHIT's 2015 environmental scan are below.

Tabula Rasa HealthCare

PHARM-GENOME-PACE (Pharmacist-Led Pharmacogenomics Service for PACE) at Tabula Rasa HealthCare (TRHC) integrates PGx into the medication therapy management and clinical care of older adults enrolled in the Program of All-inclusive Care for the Elderly (PACE). The process begins when a prescriber orders a PGx test panel of nine genes (e.g., CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP3A5, CYP4F2, VKORC1, SLCO1B1, TPMT) associated with drug pharmacokinetics (e.g., absorption, distribution, metabolism, and excretion) and drug pharmacodynamics (e.g., target). A sample for DNA extraction and genetic interpretation is collected by the provider from the participant during a scheduled visit to the PACE center where medical care is provided. The sample is sent directly to a CLIA-certified laboratory for testing and subsequently to a PGx vendor for interpreting. The results are sent to TRHC via secure file transfer protocol (SFTP) or an online portal and uploaded to a proprietary clinical decision support system (CDSS, Medication Risk Mitigation Matrix). The CDSS maps genotype results (e.g., CYP2C19*1/*17) and phenotype interpretations (e.g., rapid metabolizer) to drugs (e.g., clopidogrel) and their pharmacological pathways (e.g., CYP2C19 isoenzyme metabolism). A PGx-trained pharmacist uses the CDSS to identify drug-drug interaction, drug-gene interaction, and drug-drug-gene interaction risks. The risks are interpreted in the context of actionable gene-drug pairs, as evidence from PGx biomarkers in FDA-approved labeling or clinical practice guidelines (e.g., Dutch Pharmacogenetics Working Group [DPWG], Clinical Pharmacogenetics Implementation Consortium [CPIC]), and the participant's complete drug profile, accounting for possible phenoconversions. Utilizing the Medication Risk Mitigation Matrix, a pharmacist creates a personalized consultation and formulates participant-centered recommendations for monitoring, continuing and/or changing the drug regimen. The pharmacist sends the consultation to the ordering prescriber and uploads the final report, consisting of the PGx test results and the consultation, into the pharmacy's electronic health record, which is readily accessible to the PACE provider. The prescriber may also contact the pharmacist for a verbal explanation or further consultation.

TRHC uses SNOMED (Systematized Nomenclature of Medicine) coding in the Enhanced Medication Therapy Management program and is reviewing SNOMED codes for use in other settings.

Vanderbilt University Medical Center

PREDICT (Pharmacogenomic Resource for Enhanced Decisions in Care & Treatment) at the Vanderbilt University Medical Center facilitates effective medication use by incorporating meaningful genomic information into the electronic health record. The process begins when the provider orders a single panel of eight genes/32 common single nucleotide polymorphisms associated with drug absorption, distribution, metabolism, and/or excretion. QuantStudio 7, a genotyping tool, gets the allele information (e.g., *1/*4) for these genes. This is subsequently converted to phenotype (e.g., intermediate metabolizer) and mapped to medications (e.g., clopidogrel) in the clinical decision support engine [TIBCO](#). From TIBCO, data is transferred to the



electronic health record in Epic as paired test results – gene result and interpretation. Within Epic, the laboratory results are mapped to genomic indicators, which are incorporated into patients' charts. The indicators can then serve as triggers for alerts and reports that guide patient care. At this time, PREDICT covers the following drug genome interactions.

- Clopidogrel (Plavix) – CYP2C19
- Codeine – CYP2D6
- Simvastatin (Zocor) – SLCO1B1
- Tacrolimus (Prograf) – CYP3A5
- Thiopurine (Purinethol, Imuran, Tabloid) – TPMT
- Tramadol (Ultram) – CYP2D6
- Voriconazole (Vfend) – CYP2C19
- Warfarin (Coumadin) – CYP2C9/ VKORC1

Only information deemed to be actionable by the Pharmacy & Therapeutics Committee is made available within Epic. The rest is archived in an external database.

PGX PROCESSES

Laboratories

According to the Community Pharmacist Pharmacogenomics webpage listing, PGx services will continue to grow, and thereby, the number of laboratories performing PGx testing should increase.¹⁴ It is important that laboratories utilized for patient care are appropriately CLIA certified to assure quality.¹⁵ As noted above, a community pharmacy would need to obtain a CLIA Certificate of Waiver before providing waived tests. Pharmacies may also work with off-site laboratories to help improve patient access to laboratory tests.

Patient access to laboratory tests varies. For example, direct-to-consumer tests may be offered over the Internet by community pharmacies or provider offices or other settings. Point-of-care tests may be offered in similar settings but may require a prescriber's order. Insurers typically require a prescriber's order to cover a laboratory test. Health care practitioners providing point-of-care tests also may provide a related patient-care service (e.g., result interpretation). Ideally, laboratory test results reports should be organized and easy to understand by the health care professional and patient. However, interpretation and application of the results, as with any laboratory or device test results, should be left to a health care professional, such as a pharmacist. Unless complete medical, lab test results, and medication history, combined with a good reference library are available, more useful, specific recommendations may be problematic. LOINC (Logical Observation Identifiers Names and Codes) is the standard nomenclature for laboratory findings related to PGx.¹⁶ Although there are laboratory results in SNOMED CT, it is recommended for interoperability to use LOINC codes.¹⁷

Ordering

Some laboratories may market and provide test kits directly to the consumer, depending on state law. Ordering may depend on state law and pharmacist scope of practice for that state. In states where pharmacists may order testing, they could order the laboratory tests, perform a saliva swab,



send the sample to the lab, receive the results, then interpret and apply the results to the patient's medication therapy. Some tests are blood drawn. This sample would have to be drawn at a licensed laboratory or provider's office and probably processed from there. In the case of states where pharmacists do not have ordering privileges, a qualified provider may have to order the laboratory tests; so it would be important for pharmacists providing PGx services to have a collaborative relationship with a qualified ordering provider.

Interpretation and application of PGx testing and reporting

Pharmacists have the most pharmacology, pharmacokinetic, and pharmacodynamic training of any health care professional and are the best equipped to interpret and apply PGx testing to patient medication regimens through existing medication management services models of practice.^{18,19} Interpretation can include, at a minimum, an understanding and explanation of what the testing and reporting means at the more basic level. Interpretation and application can be utilized to an advanced, pharmacotherapy level by applying the testing to the patient's current medication therapy, assessing for medication related problems (MRPs), reviewing and relating past medication intolerances to PGx results, and projecting future direction of therapy based on the PGx testing to guide therapy.

With the more advanced and complex interpretation and application of PGx results, one can preempt MRPs, improve medication therapy efficacy, adherence, and decrease overall medical costs. This can result in decreasing ADRs, which result in decreased hospital admissions, emergency room (ER) visits, excessive physician visits, and cost related to loss of work. This can lead to sparing in many cases a valuable primary care resource and possibly associated laboratory test ordering to adjust therapies via trial and error. In this more advanced service, PGx as a primary component of individualized medicine can become real, tangible, and demonstrate quantifiable results.

Education and Clinical Counseling

Education and counseling may best be delivered through an office practice model since clinical counseling may be extensive and time consuming. If PGx testing is limited to one or a few genes, clinical education and counseling may be briefer. In the case of many genes tested in a complex polypharmacy patient, especially if taking herbal and dietary supplements, clinical counseling and education with accompanying recommendations may take much longer because the service is much more involved. If the pharmacist has prescribing privileges or laboratory test ordering privileges, these activities would also add time and complexity to the service.

BUSINESS MODEL

Financial Viability

For any product or service to continue to be available over time, the testing companies offering these should be financially viable and reputable. The PGx testing companies have already set their margins and continue to stratify themselves in the marketplace by offering different genes and number of genes to be tested; how they report results, be it directly to the consumer or to health care professionals; and by pricing and by market segmentation. PGx services offered may need to align with how the various laboratories are marketing products. Price and complexity of a particular test and how lab results are reported and results conveyed to patients will help determine the price of related PGx services.

Billing Codes

Payment for services is a dynamic process and is constantly changing. Refer to the most current payment policies for commercial and government programs. As of the end of 2019, pharmacist clinical services have emphasized primary care and chronic care management. There are Current Procedural Terminology (CPT) codes for specific test genotyping, but none are available for PGx laboratory test interpretation and clinical counseling and application. This is an opportunity for pharmacists and other health care professionals. Currently, billing for PGx services, except for possible specific testing (e.g., abacavir), is primarily fee-for-service and self-pay.

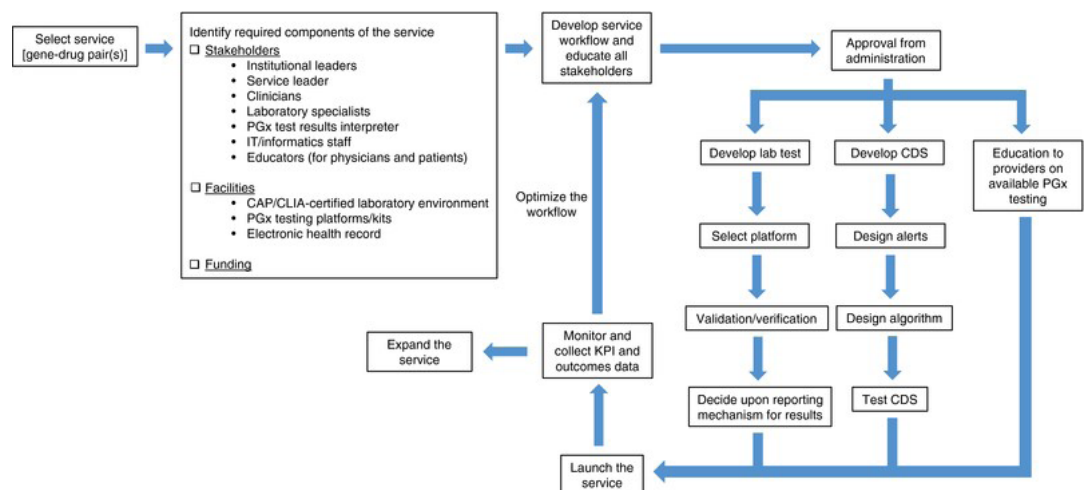
IMPLEMENTATION

As the acceptance of PGx grows, the implementation of PGx has become critical for establishing new programs that offer this service successfully. Such undertakings are often far from straightforward and require strategic planning, accompanying a systemic organizational change to embed this service into already established workflows in clinical settings.

In their article, “Implementing Pharmacogenomics at Your Institution: Establishment and Overcoming Challenges,” Arwood, Chumnumwat, and colleagues detail the required resources to have prior to implementation.²⁰ The article includes subsections that can be utilized as an assessment tool to ensure that the appropriate evidence and resources are available to establish a successful program. Since prospective PGx outcomes data is somewhat limited, it is beneficial to consider collection of prospective data once service implementation is under way, including clinical outcomes to justify the benefit of PGx services with regard to cost, savings, safety and efficacy at your institution/practice.

A PGx champion, which can include a pharmacist, is a key resource in developing a new service. This role is critical in bringing in stakeholders such as clinicians, laboratory personnel, information technology personnel, students, clinical staff, administration, and other key members of the team so they can inform the process and the implications of rolling out a new service.

The following flowchart shows the key steps involved in an implementation plan.²¹



A key stakeholder not described in the figure central to the service is the patient. It is critical to consider the education needs of patients in PGx testing so that they understand the potential costs, benefits, and risks of PGx testing.



INFORMATICS

The application of PGx in practice is highly dependent on the adoption of health IT standards. Organizations such as Health Level 7 (HL7), the National Council for Prescription Drug Programs (NCPDP), and the Pharmacy Health Information Technology (PHIT) Collaborative have mechanisms in place to develop and maintain standards that support interoperability and data reporting. To fully leverage technology, such as artificial intelligence (AI) and machine learning, standards must be implemented by technology vendors, payers, and pharmaceutical manufacturers. This will require a high level of participation in standard development processes by stakeholders across the health care industry.

Fast Healthcare Interoperability Resources (FHIR) is an evolving HL7 standard that is seeing increased adoption across the industry. FHIR uses RESTful APIs, which may be new to health care, but are used to support many other industries that live on the World Wide Web. Ongoing initiatives are in place to determine how FHIR can be applied to achieve the goals of the Precision Medicine Initiative.²² Stakeholders should monitor the FHIR standard closely and consider implementation opportunities.

A new FHIR resource, MolecularSequence, was developed within the existing framework to facilitate this effort. It stores genetic sequences as clinically relevant blocks. Consistent with the FHIR philosophy, MolecularSequence is compatible with other resources through genetics profiles. For example, Observation, Diagnostic Report, Service Request, and Family Member History genetics profiles can all facilitate display and reporting of genetic information captured by MolecularSequence. In complex cases, extensions can be used to link out to a patient's full genetic sequence.²³

Standard Terminology

Best practices begin with standardizing terminology used by providers, laboratories, informaticists, payers, and industry stakeholders. Many laboratories perform PGx testing. However, when test results are reported in software systems, clinical terms that have the same interpretation for a genotype or phenotype may be displayed in different ways. Members of the Clinical Pharmacogenetics Implementation Consortium (CPIC) did a substantial amount of work to standardize the terminology used across different laboratories.²⁴ This work ensures all stakeholders refer to a common framework for PGx clinical terms. It is critical that all laboratories and stakeholders abide by a common framework to avoid terminology variability.

Standard terms should be captured in practice using standard data elements, also known as documentation codes. CMS' Meaningful Use established a standardized framework for clinical documentation. Leveraging terminologies such as SNOMED CT, LOINC, and RxNorm allow data to flow freely between software platforms and minimize the complexity of aggregate reporting.

Common PGx terms must have corresponding standard data elements. CPIC is also making progress on this front. Many genetic laboratory tests and results can be ordered and reported using LOINC. Laboratory results must be interpreted and presented in software systems using standard terminology. Data elements representing genotypes and phenotypes should be documented using SNOMED CT. When all software systems use a common set of data elements (e.g., value set) to capture PGx information, data can be exchanged and reported consistently across all organizations and practice settings regardless of the software vendor. As the field of PGx continues to progress, a significant amount of work is required to ensure standard data elements are created and maintained.

There are a growing number of SNOMED CT codes available for documenting PGx information. These include codes for documenting care provided, such as:

TYPES OF SERVICES PROVIDED	
428931000124102	Pharmacogenetic consultation (procedure)
453971000124106	Evaluation of pharmacogenetic result (procedure)
452891000124105	Pharmacogenetic medication review (procedure)

MEDICATION INTERVENTIONS	
453281000124103	Medication dose changed in response to pharmacogenetic findings (situation)
454251000124108	Medication dose too low based on pharmacogenetic finding (finding)
454231000124101	Medication dose too high based on pharmacogenetic finding (finding)

EXAMPLES OF CODES WITH DETAILED INFORMATION FOR CODING METABOLISM TYPES	
738532000	Cytochrome P450 family 2 subfamily D member 6 poor metabolizer (finding)
738533005	Cytochrome P450 family 2 subfamily D member 6 intermediate metabolizer (finding)
738534004	Cytochrome P450 family 2 subfamily D member 6 normal metabolizer (finding)
738535003	Cytochrome P450 family 2 subfamily D member 6 ultra-rapid metabolizer (finding)
738539009	Thiopurine S-methyltransferase poor metabolizer (finding)
738540006	Thiopurine S-methyltransferase intermediate metabolizer (finding)
738541005	Thiopurine S-methyltransferase normal metabolizer (finding)
738786005	Cytochrome P450 family 2 subfamily C member 19 poor metabolizer (finding)
738788006	Cytochrome P450 family 2 subfamily C member 19 normal metabolizer (finding)
738789003	Cytochrome P450 family 2 subfamily C member 19 rapid metabolizer (finding)
738790007	Cytochrome P450 family 2 subfamily C member 19 ultra-rapid metabolizer (finding)

PROVIDER TYPE	
720505003	Pharmacogenomic specialist (occupation)

Data Models, Reporting, and Interoperability

Once standard data elements are identified, they must be structured appropriately, readying systems for exchange and reporting. The National Library of Medicine (NLM) collates standard data elements as open-source value sets housed in the Value Set Authority Center (VSAC). Value sets aid implementation of standard data elements within standard data models. The Quality Data Model (QDM) is the current standard for structuring data in certified EHRs. QDM supports electronic clinical quality measure (eCQM) reporting and allows the U.S. government to measure value across federal health programs. Reporting standards also support population health research and analytics.

Interoperability standards such as HL7 Consolidated Clinical Document Architecture (C-CDA) depend on standard terminology to share data across health information exchange (HIE) networks.



This allows providers to send information to other members of the care team seamlessly throughout the course of care and during care transitions. All certified EHRs are required to accommodate the C-CDA standard; however, changes are required to support the exchange of PGx information.

POLICY / REGULATORY ISSUES

At the federal level, different agencies have oversight authority over various elements related to pharmacist-provided services in the field of PGx, including development, coverage and reimbursement of tests, and software used in PGx. In addition, federal agencies and the private sector are engaged in efforts to increase data relevant to PGx tests and their clinical application. While state law generally dictates pharmacists' scope of practice, federal laws and regulations related to Medicare and patient privacy are examples of federal oversight that impacts patient access to pharmacist-provided PGx services.

State Law

State laws, including scope of practice laws and regulations (i.e., those regarding collaborative practice agreements and the pharmacist's ability to order and interpret laboratory tests), directly influence the pharmacist's ability to perform services related to PGx and the scope of those services. Alternatively, state law may dictate the patient's ability to independently order laboratory tests, such as genetic tests. Thus, patient access to laboratory tests also varies by state. State variation also exists regarding those practitioners who are considered laboratory personnel, among other topics more closely related to performing the test in question. This paper will not delve into state-level policy.

Federal Law – Medical Devices and Laboratories

It is important to be aware of the types of tests and settings in which genetic tests/devices are performed, as they may pose different legal, regulatory, policy, and practice issues. The FDA regulates some tests (typically more complex tests) and devices (e.g., in vitro diagnostics, companion diagnostics) as medical devices. Other tests are considered lab-developed tests (LDTs), which are subject to CMS oversight based on the agency's authority to regulate laboratories. Certain LDTs or devices may be used in CLIA-waived settings, such as pharmacies.

The scope of FDA's oversight of lab-developed tests remains an ongoing point of debate. Legislative proposals have been introduced to provide clarity regarding oversight of lab-developed tests, but as of this writing, such legislation has not passed. Topics that may be impacted by a legislative change include test development, approval processes, manufacturing, laboratory operations, labeling, medical use, and interpretation, among other topics.

FDA also has oversight of certain medical software (as a medical device), some of which may be used to provide clinical decision support or help interpret results.²⁵ When such authority was provided, several different clinical decision support functions were excluded from the definition of device. In 2017, draft guidance from FDA clarified that devices, which include algorithms to analyze or interpret genomic data, would likely be subject to FDA regulation. Therefore, pharmacists relying on CDS tools that include algorithms to analyze or interpret genomic data may consider whether FDA has approved the tool and whether FDA approval was needed.

Federal Data Sources

FDA defines and categorizes biomarkers and has two regulatory pathways for biomarker acceptance in drug development. A drug's label may include information (e.g., drug exposure description, clinical response variability) regarding genomic biomarkers. FDA has made available a list of therapeutic products with PGx information found in the drug labeling, and some of the content includes specific action to take based on the biomarker information. Generally, the table



does not include biomarkers used to diagnose genetic diseases unless the information may impact a prescribing decision. FDA guidance regarding labeling (e.g., clinical pharmacology section of labeling) has also addressed inclusion of PGx information.²⁶

CDC Office of Public Health Genomics

The Centers for Disease Control and Prevention (CDC) Office of Public Health Genomics (OPHG) maintains a database of genetic tests that are placed in one of three tiers based on certain criteria.²⁷ The tiers are outlined below.²⁸ OPHG ranks genomic tests and family health history application by levels of evidence. The database may provide helpful information for pharmacists interested in determining the clinical utility of PGx and related services.

Tier 1/Green	Tier 2/Yellow	Tier 3/Red
<ul style="list-style-type: none">• FDA label requires use of test to inform choice or dose of a drug• FDA cleared or approved companion diagnostic device• CMS covers testing• Clinical practice guidelines based on systematic review supports testing	<ul style="list-style-type: none">• FDA label mentions biomarkers• FDA premarket approval (PMA)• FDA 510(k) substantially equivalent decision• CMS coverage with evidence development• Clinical practice guideline, not based on systematic review, supports use of test• Clinical practice guideline finds insufficient evidence but does not discourage use of test• Systematic review, without clinical practice guideline, supports use of test• Systematic review finds insufficient evidence but does not discourage use of test• Clinical practice guideline recommends dosage adjustment, but does not address testing	<ul style="list-style-type: none">• FDA label cautions against use• CMS decision against coverage• Clinical practice guideline recommends against use of test• Clinical practice guideline finds insufficient evidence and discourages use of test• Systematic review recommends against use• Systematic review finds insufficient evidence and discourages use• Evidence available only from published studies without systematic reviews, clinical practice guidelines, FDA label or CMS labels coverage decision

Coverage

Payer coverage of PGx tests varies and patients may pay out-of-pocket for the test and related services. Coverage of pharmacist-provided PGx services, including medication management services, varies by payer and is distinguishable from reimbursement of a laboratory test. In addition, payer coverage of tests may vary based on the type of test and the circumstances under which a test will be covered. Payers do not generally cover patient-ordered tests unless the test is recognized as preventive (e.g., recognized by the U.S. Preventive Services Task Force) and other requirements are satisfied.

In 2018, Medicare released a national coverage determination (NCD) allowing coverage of tests approved by the FDA or cleared as part of a companion in vitro diagnostic where the test identifies the patient population most likely to benefit from therapy and provides information on the safe use



of the product.²⁹ While this does not allow coverage for all genetic testing available, it could provide an incentive for the development of additional testing.

Medicare also covers some PGx tests as diagnostic laboratory tests. The Medicare Coverage Database provides information regarding Medicare coverage decisions. CMS' Clinical Laboratory Fee Schedule dictates payment for outpatient clinical laboratory services. The laboratory test fee schedule also includes billing codes. When a single test produces results for multiple genes, laboratories often "stack" billing, with multiple Healthcare Common Procedure Coding System (HCPCS) codes included for one test. CPT and HCPCS codes have yet to be developed to account for both the PGx test performed and related services. As utilization of PGx tests becomes more common in health care, there is a greater need to understand how to document these tests for the purposes of billing, reimbursement, and recordkeeping. This results in a heightened need to use appropriate codes, ontologies, and health care data exchange standards.

Non-Discrimination

The Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination in health coverage (Title I) and employment (Title II) based on genetic information. The law sets minimum standards to protect against discrimination. According to the Department of Health and Human Services, "GINA, together with already existing nondiscrimination provisions of the Health Insurance Portability and Accountability Act, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates or preexisting conditions."³⁰ Not all of GINA's health coverage nondiscrimination protections apply to all entities. Those who are covered by the law may seek research exceptions under certain conditions.³¹ GINA also allows states to enforce more stringent laws and regulations.

LOOKING AHEAD

Innovation via Standardization

Once a robust data model is in place, the real potential of PGx can be realized. Imagine a comprehensive battery of PGx results structured in software systems to leverage CDS, AI, and machine learning. For example, a clinician prescribing a therapy can be informed about a genetic mutation, corresponding phenotype, and presented with the recommended dose or alternative therapy based on clinical guidelines. Perhaps a cancer patient is an ideal candidate for a new therapy based on their genetic profile. Software can direct clinicians to order the appropriate test for evaluation or present this therapy option if the genetic information is present in the patient profile. Applying clinical algorithms to structured PGx data will influence treatment decisions, eliminate harmful events, improve health outcomes, and reduce cost.

PGx information can also be used for research. Information gained will lead to optimizations of current treatment regimens and discovery of new therapies, personalizing treatment for each unique patient. This will be most powerful when the patient's genome is sequenced and documented in a structured way within the clinical software systems.

Privacy & Security

As the field of PGx continues to evolve, it is of highest importance to have thorough data security protections and practices in place. Genetic data is private. Every person deserves to be informed and dictate how their clinical information is used within and outside of health care organizations. Stakeholders should follow recommended industry standards for data privacy and security.



Government officials should continue to discuss and implement changes that support innovation without compromising the well-being of people.

The PGx revolution will yield major advances in health and science. Data standards provide a solid foundation for a strong, technology-driven ecosystem driving innovation for many years. To ensure this future is realized, stakeholders must actively participate in the standards development process, support collaboration between government and private industry, and design programs that align economic incentives while maintaining the highest standard of ethics.³²

Population Health

With newborn screening being the most established precision medicine public health program in the United States, there are also opportunities to systematically screen for other common genetic and inheritable conditions, such as breast cancer, ovarian cancer, and Lynch syndrome.³³

In precision public health, technological advancements provide opportunities to analyze big data in order to prevent disease, promote health, and reduce health disparities in populations.³⁴

Organizations such as the [Global Alliance for Genomics & Health](#) created tools and standards for genomic data, regulatory issues, ethics, and data security. This responsible sharing of genomic data with a patient's medical record has the potential to identify patients that share similar signs and symptoms.

Commercializing

Access to better PGx and other health information can lead to better health care outcomes for most patient populations. Challenges ahead are dependent on electronic interfacing at the point of care where the clinician sees the patient. Current technology exists, but interfacing would have to be more standardized to make electronic health information more available. Improvements in payment for PGx services would also need to be expanded. With regard to pharmacist clinical PGx services, providing these to their full potential rests on sustainable reimbursement.

Scaling of such efforts has been accomplished by 23andMe® by providing direct-to-consumer genetic testing. Regeneron Pharmaceuticals Genetics Center and Geisinger Health System have partnered to connect the exome sequence with medical records data for hundreds of thousands of patients.³⁵ In addition, IBM's Watson for Genomics technology is currently assisting oncologists by providing information to help identify precision oncology treatment options.³⁶



4. RESOURCES

The Accreditation Council for Pharmacy Education (ACPE) states in its 2016 *Standards and accompanying Guidance on Standards* the following required competencies related to PGx in an accredited Doctor of Pharmacy (PharmD) curriculum:

In Appendix 1: Required Elements of the Didactic Doctor of Pharmacy Curriculum.³⁷

- Pharmaceutical sciences—Pharmacogenomics/genetics: “Genetic basis for disease and individual differences in metabolizing enzymes, transporters, and other biochemicals impacting drug disposition and action that underpin the practice of personalized medicine.”
- Clinical sciences—Pharmacotherapy: “Evidence-based clinical decision making, therapeutic treatment planning, and medication therapy management strategy development for patients with specific diseases and conditions that complicate care and/or put patients at high risk for adverse events. Emphasis on patient safety, clinical efficacy, pharmacogenomic and pharmacoeconomic considerations, and treatment of patients across the lifespan.”

In Appendix B: Entry-level Competencies Needed for Community and Ambulatory Care Pharmacy Practice.³⁸

- Pharmacist-delivered patient care: “Describe personalized medicine and apply an individual patient’s genetic profile to the selection and modification of a medication regimen.”

The *Journal of the American Pharmacists Association* published “Pharmacogenomic competencies in pharmacy practice: A blueprint for change,” in 2017, outlining their own recommended standards for the Doctor of Pharmacy curriculum. Their fifteen recommended competencies are organized into four domains: Basic genetic concepts, Genetics and disease, Pharmacogenetics and pharmacogenomics (three competencies described above), and Ethical, legal, and social implications.³⁹

The *Pharmacogenomics* journal published “Strategies for implementation of an effective pharmacogenomics program in pharmacy education,” in 2017, proposing the following four strategies for implementation:⁴⁰

- College-level genetics should be required as an admission prerequisite to a college of pharmacy. At the time of publication, only 8/134 programs currently had this requirement. Courses should include both traditional genetics topics as well as a laboratory component in genetic techniques.
- Genetics and pharmacogenomics should be an integrated core course included in Doctor of Pharmacy didactic curriculum. Courses should consider using the ACCP-published textbook of pharmacogenomics, or another text of equal quality.
- Experimental research laboratory rotations should be included in the Doctor of Pharmacy curriculum. Most schools are not equipped to provide the option of participation in basic pharmacogenomic research, but use of bioinformatic software (e.g., GeneScription) may help fill this gap.



- Proposed courses and educational content are delivered by experts. Pharmacogenomics is typically delivered as part of pharmacotherapy and is taught by faculty who do not have any exposure to this specialized discipline. Utilizing continuing education for faculty can help to fill this gap until content experts with demonstrated experience are available.

In 2011, the National Human Genome Research Institute (NHGRI) of the National Institutes of Health (NIH) held a two-day meeting in which representatives from many national pharmacy associations and government entities collaborated to propose five genomic education needs for pharmacists:⁴¹

- Terminology: Standardized terminology is needed to facilitate effective information exchange during the creation of education programs, clinical guidelines, and other practice standards.
- Knowledge: Individuals should start their Doctor of Pharmacy program with a basic scientific foundation adequate to build competency in pharmacogenomics.
- Interpretation: Students and pharmacists must be able to utilize pharmacogenomic results and assess clinical outcomes.
- Communication: Students and pharmacists must be able to communicate pharmacogenomic information in a way that is usable to the listener.
- Professionalism: Incorporate pharmacogenomics information and skills into the professional practice of pharmacists.

PGx RESOURCES	DESCRIPTION
HTTP://WWW.CPICPGX.ORG	CLINICAL PHARMACOGENETICS IMPLEMENTATION CONSORTIUM (CPIC)
HTTP://WWW.PHARMGKB.ORG	PHARMACOGENOMICS KNOWLEDGE BASE: RESOURCE FOR CLINICIANS AND RESEARCHERS
HTTPS://WWW.GENOME.GOV/	IGNITE: IMPLEMENTING GENOMICS IN PRACTICE. NIH-FUNDED NETWORK PROVIDING RESOURCES TO CLINICIANS AND PERFORMING COLLABORATIVE RESEARCH.
HTTP://GENOMICSEDUCATION.NET/	GENETICS/GENOMICS COMPETENCY CENTER: EDUCATIONAL RESOURCES FOR GROUP INSTRUCTION OR SELF-DIRECTED LEARNING BY HEALTH CARE EDUCATORS AND PRACTITIONERS
HTTPS://WWW.NATURE.COM/TPJ/	THE PHARMACOGENOMICS JOURNAL: FOCUS ON ORIGINAL RESEARCH ON PHARMACOGENOMICS AND ITS CLINICAL APPLICATIONS
HTTPS://WWW.FUTUREMEDICINE.COM/JOURNAL/PGS	PHARMACOGENOMICS JOURNAL (FUTURE MEDICINE): FOCUS ON TOPICS THAT HAVE THE MOST DIRECT RELEVANCE TO THE PHARMACEUTICAL INDUSTRY AND WIDER CLINICAL COMMUNITY



PGx RESOURCES	DESCRIPTION
HTTPS://STORE.ASHP.ORG	ASHP CONCEPTS IN PHARMACOGENOMICS, 2ND EDITION. THE NEW EDITION COVERS BOTH THE FUNDAMENTALS OF PHARMACOGENOMICS, THERAPEUTIC APPLICATIONS, AND THE LATEST GENOMIC TECHNOLOGIES. WRITTEN BY PHARMACISTS AND GENETICISTS, IT NOT ONLY COVERS BASIC SCIENCE CONCEPTS BUT ALSO INCLUDES EXPANDED COVERAGE OF THERAPEUTIC APPLICATIONS. EACH CHAPTER FEATURES KEY DEFINITIONS, CASE STUDIES, AND CLINICAL PEARLS, WITH FIGURES AND SUMMARY TABLES TO FURTHER SUPPORT LEARNING.
HTTPS://WWW.ASHP.ORG/PHARMACY-PRACTICE/RESOURCE-CENTERS/	ASHP RESOURCE CENTER IS AN AREA FOR PHARMACISTS TO OBTAIN ADDITIONAL INFORMATION AND RESOURCES ABOUT PHARMACOGENOMICS AND RELATED TOPICS

TRAINING OPPORTUNITIES	DESCRIPTION
HTTPS://WWW.AACP.ORG/RESOURCE/GRADUATE-DEGREE-PROGRAMS-PHARMACY-AND-PHARMACEUTICAL-SCIENCES	AACP LIST OF GRADUATE DEGREES IN PHARMACY AND PHARMACEUTICAL SCIENCES IN THE US: SPECIFIC PGX EXAMPLES AT UCSF (PHD) AND MANCHESTER UNIVERSITY (MS)
HTTP://GENOMICSEDUCATION.NET/	ASHP ONLINE RESIDENCY DIRECTORY: SPECIFIC PGX EXAMPLES AT UF (PGY2) AND ST. JUDE'S (PGY2).
HTTPS://WWW.NACDS.ORG/PHARMACOGENOMICS-CERTIFICATE-PROGRAM/	TEST2LEARN COMMUNITY-BASED PHARMACOGENOMICS CERTIFICATE PROGRAM. NACDS AND UNIVERSITY OF PITTSBURGH PROVIDE A 20 HOUR CONTINUING EDUCATION COURSE FOR PRACTICING PHARMACISTS.
HTTP://PHARMACOGENOMICS.UCSD.EDU/	PHARMGENED: PHARMACOGENOMICS EDUCATION PROGRAM. MATERIALS CURATED BY UNIVERSITY OF CALIFORNIA, SAN DIEGO (UCSD) SKAGGS SCHOOL OF PHARMACY AND PHARMACEUTICAL SCIENCES.
HTTPS://WWW.JAX.ORG/EDUCATION-AND-LEARNING	THE JACKSON LABORATORY: ONLINE PROGRAMS AND RESOURCES, IN-PERSON INTERACTIVE WORKSHOPS, AND LEARNING OPPORTUNITIES FOR DIVERSE HEALTHCARE PROVIDERS
HTTP://WWW.RXGENOMIX.COM/COURSES/PHARMA	APHA ADVANCED TRAINING PROGRAM IN PHARMACOGENOMICS, DEVELOPED IN CONJUNCTION WITH RXGENOMIX AND MANCHESTER UNIVERSITY
HTTPS://ONLINEPM.PHARMACY.UFL.EDU/PROGRAMS/CONTINUING-PHARMACY-EDUCATIN/	UNIVERSITY OF FLORIDA CLINICAL APPLICATION OF PHARMACOGENOMICS COURSE SERIES



TRAINING OPPORTUNITIES	DESCRIPTION
HTTPS://PHARMACY.CUANSCHUTZ.EDU/ACADEMICS/CONTINUING-EDUCATION/CERTIFICATE-PROGRAMS#PHARMACOGENOMICS	UNIVERSITY OF COLORADO PHARMACOGENOMICS CERTIFICATE PROGRAM
HTTPS://WWW.SU.EDU/PHARMACY/PROGRAMS/PHARMACOGENOMICS-PRECISION-MEDICINE-CERTIFICATE/	SHENANDOAH UNIVERSITY PHARMACOGENOMICS & PERSONALIZED MEDICINE CERTIFICATE
HTTPS://WWW.PHARMACY.UMN.EDU/CENTERS-AND-INSTITUTES/PERSONALIZED-MEDICINE/NEWS-EVENTS/PHARMACOGENOMICS-CONFERENCE-2020	UNIVERSITY OF MINNESOTA COLLEGE OF PHARMACY PHARMACOGENOMICS CONFERENCE 2020 (ALL CONFERENCE MATERIAL IS AVAILABLE FOR ONE YEAR POST CONFERENCE).
HTTP://ELEARNING.ASHP.ORG/PRODUCTS/6673/PHARMACOGENOMICS-CERTIFICATE-PROGRAM	ASHP PHARMACOGENOMICS CERTIFICATE PROGRAM

5. CONCLUSION

Inclusion of PGx in standard of care can improve patient outcomes and lower health care costs. With PGx, clinicians can proactively and more precisely identify the most effective medications and dosages that also minimize waste and adverse reactions. Despite ongoing research and a steady output of discoveries in this field, incorporation in standard of care is limited. There are regulatory, financial, and technical challenges. Fee for service reimbursement for PGx remains challenging. However, as more evidence demonstrates value in improving patient care, inclusion in payment structures should improve. Training programs and business models must adapt accordingly. Clinical and operational workflows—even how patients engage with their medical information—need to evolve over time. Having a solid foundation that facilitates adoption and future growth is critical. A number of organizations, such as the federal government, CPIC, and HL7 International, have workgroups and ongoing initiatives to establish this infrastructure and promote standardization where possible. Individual institutions have also pioneered care models that incorporate PGx with reasonable success. There is strong potential for current and future opportunities for pharmacists to use PGx to optimize drug therapies, as experts in the medication-use process.

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7. APPENDIX

7.1 PHARMACISTS' PATIENT CARE PROCESS

This figure depicts a standardized pharmacist patient-centered collaborative care process for pharmacists providing patient care services.⁴² The pharmacists' patient care process described in this illustration was developed by examining a number of key source documents on pharmaceutical care and medication management services. Patient care process components in each of these resources were catalogued and compared to create the following process that encompasses a contemporary and comprehensive approach to patient-centered care that is delivered in collaboration with other members of the health care team.

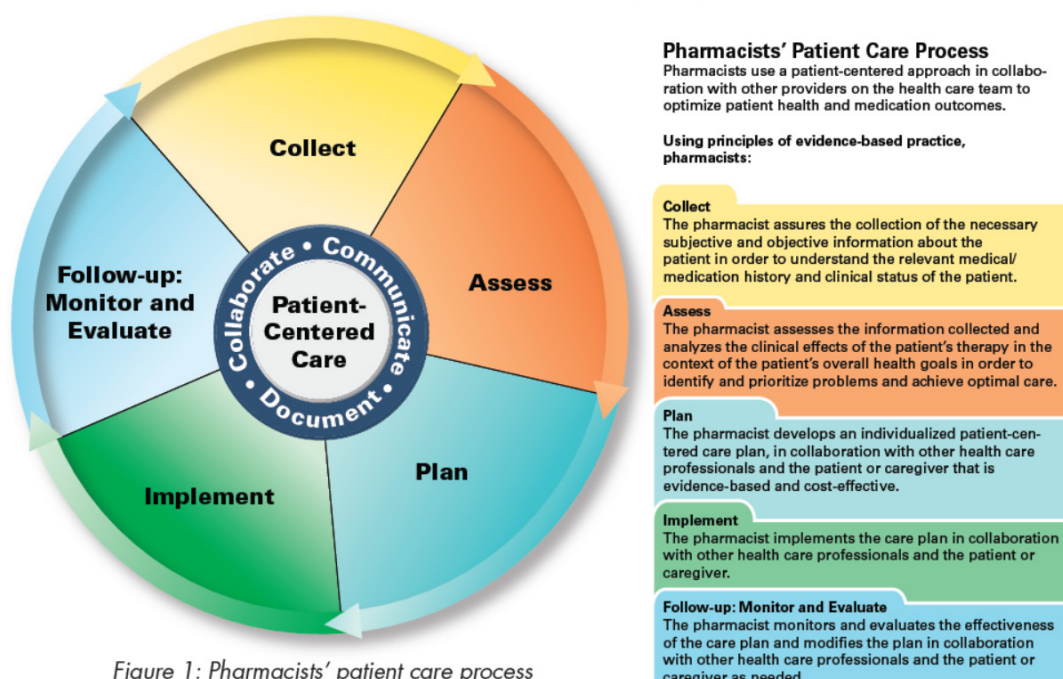


Figure 1: Pharmacists' patient care process

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