**What are the minimum pre-test patient counselling points:**

At a minimum, the process should be designed to ensure the following points are addressed:

• The patient’s health and medication history are obtained.

• The patient is asked about their rationale for seeking PGx testing and whether there are any pending therapeutic selections for which it may be used.

• The patient is counselled on:

• What genetic variations and their DNA can affect their body.

• How these genetic differences can influence the effect of medications.

• Limiting factors of PGx testing including which genes and medications will be covered by the test and the type of information that will not be covered.

• Potential risks of genetic testing, including genetic discrimination.

• The Genetic Information Non-discrimination Act, the specific protections it provides and how their privacy is ensured.

• How the test is to be performed and when they will receive their results and recommendations.

• What to do with their results when they arrive and how they will be integrated into the health system.

• The patient is provided opportunities to ask questions throughout the session.

• The patient is prompted to ask clarifying questions through open-ended prompts by the counsellor.

• The patient and pharmacist discuss a follow-up plan. This could include when the patient is to receive their results or discuss scheduling appointments with the PGx.

program or their primary care provider.

• The patient should also be advised where to direct questions or concerns that arise following the counselling session and directed to any other educational resources

that are pertinent based on the discussion.

**What are the core elements and structure of a pharmacogenomics counselling session checklist:**

Purpose and benefit of pharmacogenomic (PGx) testing:

1. Gives extra information to help predict drug response

2. Helps with drug selection, side effects, efficacy, dose

3. Lifetime result

4. Future application of genotype results

Genetic concepts:

1. Relationship between gene and drug response (DME, drug transporter, drug target)

2. Inherited basis of drug response

3. Provide visuals

X-ample (“example”):

1. Use an example from patient’s medication list to further help the patient understand

connection between genes and drug response

2. Counsellor may also use examples from their own genetic results if known

Drawbacks of pharmacogenomic testing:

1. Research is incomplete. Not every medication is linked to a gene that can predict drug.

response, including herbals and OTCs. Some genes captured on panel may not have enough.

information yet to guide treatment.

2. Many factors affect drug response (kidneys, liver, age, weight, drug interactions)

3. ‘Normal’ (those with no change from the expected activity) or wildtype genotype results still

warrant standard precautions and negative outcome are a possibility.

4. While current testing captures the most common genes known to influence drug response

and known variants in each gene, additional testing may be warranted if a new gene is

discovered and not on the original panel.

5. PGx testing cannot tell you with 100% certainty which medication will or will not work or whether you will get a side effect

Risks and concerns:

1. Genetic Information Non-discrimination Act (GINA)

2. Health Insurance Portability and Accountability Act (HIPAA)

3. How samples are stored and whether they can be used for any other testing or research

4. Pharmacogenomic testing does not tell us your risk of a disease

5. Other treatment or testing options that could eliminate the need for a genetic test

Understand patient’s view of pharmacogenetic testing:

1. Check in to see if patient has questions or needs clarification or to summarize their

understanding

Game plan and process:

1. Buccal sample sent to lab

2. Turnaround time

3. Review of results at follow up visit

4. Financial responsibility

Sharing pharmacogenomic results:

1. Patient summary to keep and share with providers outside of health system

2. Communicate results with pertinent providers

3. Coordinate care with clinical team as needed

4. Placement of results into electronic health record and tools available to providers

5. Availability of patient portals for access to test results

**What benefits of PGx testing can we tell patients so that they can understand:**

Adverse effect:

“If there is a change in your DNA that causes the gene to produce fewer proteins then your body could break some medications down slower leading to a higher chance of side effects as the medications ‘builds up’.”

Therapeutic Efficacy:

“If your body is producing too many of these proteins then you might work through medications too quickly to really get a benefit from them.”

PGx results are life-long results:

“These results are life-long results. However, as tests change, and new genes are researched you may be asked or want to perform further PGx testing in the future. The laboratory reference sheet at the end of the report will be your best resource for determining if other testing could provide benefits.”

Benefits outside of initially ordered indication:

“Some genes, like CYP2D6 and CYP2C19, can provide information on multiple drug classes. For instance, these same genes can be involved in antidepressant medications, opioid pain medications, antipsychotics, proton pump inhibitors and nerve pain medications.” (Most patients don’t cite a specific disease state or gene of interest)

**What limitations of PGx testing can we tell patients so they can understand:**

Does not cover all medications:

“We do not have studies and literature linking genes to all of these medications.”

Negative predictive test:

“Another limitation of the test I. that it cannot guarantee that a medication will work for you. We won’t be able to look at the test results and say ‘We should use drug x at dose y.’ What the test can tell us is which medications we can remove from our initial list of options.”

Only one part of the medication selection process:

“This is testis only one of several tools that you and your provider may use to determine which therapies may be best for you. Diet, exercise, health conditions and other medications may affect how a medication will work for you.”

May not catch rare variations:

“Here is a sheet that describes what genes we tested and which spots on those genes we looked. You may want to do another genetic test in the future and this information can help you determine whether our test may have missed something that the new test would be able to find.”

Genes with limited evidence:

“Some genes have not been studied well enough for us to make recommendations based upon their results. This may change as more studies are done and we learn more about the links between gene variations and medication response.”