Question: Is performing Pharmacogentic Testing ("PGT") on my pain management patients legally required and if not, what are the reasons for performing the test?

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Pharmacogenetic testing ("PGT") is a laboratory test performed on a sample of a patient's DNA that provides information about whether a patient has a genetic predisposition to metabolize medications differently from normal metabolizers. PGT results categorize patients into one of four metabolic phenotypes:

1. Ultra-rapid metabolizer
2. Extensive metabolizer
3. Intermediate metabolizer
4. Poor metabolizer

Based on this categorization, extensive metabolizers are considered normal. Approximately one out of five patients are poor or ultra-rapid metabolizers. In some patient populations more than 40% of patients will be something other than extensive metabolizers. Put another way, approximately 4 out of 10 patients can be at increased risk for either toxicity or decreased efficacy of prescribed controlled substance medications, including opioids, benzodiazepines, and some other medications. In the worst cases, patients can have a dangerous reaction to a medication simply because they metabolize medications differently from the normal population. The goal of PGT is to utilize the metabolic classification of patients to identify genetic reasons for and the risks of an unexpected outcome, and to decrease future toxicity.

There is currently no legal requirement to perform PGT on patients. However, the failure to perform PGT can expose providers to added risk of licensure action and liability or may put patients at risk by limiting the providers' ability to effectively treat their patients.

Licensure

Given the increased scrutiny on pain management providers and specifically, their prescribing patterns, providers are having to justify the dosing and quantities of the controlled substance medications they prescribe. Often, a state-contracted physician reviews the provider's medical records with no personal experience with the particular patient, and makes a determination as to whether the dosing and quantity of controlled substance medications prescribed to the patient were appropriate. In the end, because the state's physician reviewer is deemed "independent", his/her conclusion is presumptively correct. To be more specific, if the state's physician reviewer disagrees with the dose and quantity of controlled substance medication that you have prescribed, that conclusion, whether correct or incorrect, places you in the precarious position of arguing that you, the physician whose records are in question, are correct and the independent "expert" hired by the state is incorrect. If there were uniform agreement about what constitutes a proper dose and quantity of controlled substance medication, then this risk would be negligible. However, because pain is subjective and patients' responses to pain differ, universal prescribing protocols do not apply.

PGT provides objective analysis to support clinical decision-making, and specifically, dosing and quantities. For example, a patient whose PGT results show that he is an ultra-rapid metabolizer may require higher dosing or quantities of controlled substance medications in order

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to have the same efficacy experienced by an extensive (normal) metabolizer. Where the physician reviewer's disagreement with a prescribed dose or quantity may be based on his/her experience and education, prescribing based on the patient's PGT result is specific and more clinically accurate. As such, utilizing PGT to determine appropriate prescribing for patients adds a component of individualized certainty to the prescribing decision that is otherwise filled with subjective components and diminishes the strength of any dissent that is based purely on education and no specific interaction with the patient. Simply stated, a one-time PGT performed on each patient for whom controlled substances will be prescribed on a long-term basis can provide objective evidence to support the provider's prescribing decisions that cannot be refuted merely by an expert's opinion that does not contain scientific contradictory evidence.

Limiting Legal Liability

Legal liability in medical malpractice is based on the theory that a provider had a duty to act in a particular manner and failed to act in that manner such that the failure caused injury to the patient (the basic negligence cause of action). A duty is created where there is a physician-patient relationship. The duty owed to the patient is to provide the level of care that the average reasonable physician in a comparable specialty, location, and available knowledge would provide to his/her patient. This means that physicians are expected to practice at the level of the community standard, in compliance with laws and regulations, and based on the information available that would reasonably influence the physician's practice. Because of the "reasonableness" standard, there can be much disagreement about what is and what is not reasonable. When there is an issue of liability, it is because something bad already happened. As such, the question is no longer what did you do to prevent the bad thing from happening, but rather, **"what information was available that could have prevented the bad thing from happening?"**

In the case of an adverse drug reaction or a harmful drug-drug interaction, the cause is known. The question of the physician, as noted above, is not what you knew, but what you could have evaluated that would have prevented the event from happening. Imagine a case where you prescribe your patient a typical quantity and dosage of a controlled substance medication for chronic non-malignant pain. In the normal metabolizer population, the patient may be able to take the medication as prescribed without incident. In this case, however, your patient is one of the 40% of the population who is not an extensive metabolizer and as a result, your patient experiences a dangerous cross-reactivity with another drug you prescribed and becomes comatose with a poor prognosis. Had PGT been performed, you would have been aware of the potential for the negative drug-drug interaction and would have prescribed a different regimen.

The patient's family files suit against you alleging malpractice. Did you breach your duty of care by failing to obtain a PGT result prior to prescribing controlled substances? There is no clear answer, however, there are some significant factors that can be used against you:

1. The results obtained from PGT would have prevented the adverse reaction experienced by your patient.
2. There is a significant amount of research available for physicians regarding adverse drug reactions due to different metabolism of patients.
3. PGT is commercially available and offered by several laboratory companies.

4. PGT is being used by other physicians prior to prescribing controlled substance therapy and therefore, is some evidence of a "standard of care".

Two additional factors to remember when evaluating the potential for liability:

1. When a patient has suffered an injury that could have been prevented by the physician, juries comprised of the lay public are generally not sympathetic to excuses for not preventing the injury.
2. Even if you are successful in defending this claim, lawsuits take a financial and reputational toll and require significant time away from your practice.

Some physicians have intimated that a "don't look" approach may be helpful in mitigating exposure to liability. This is best answered by analogy: If you come to a stop sign where there is a car on your left, even if you choose not to look at the car or acknowledge its existence, it does not change the fact that the car is there and failure to adjust to that car is likely to have catastrophic results. Simply put, you cannot escape liability for a bad outcome by pretending to not see something if seeing it would have avoided the bad outcome.

The "don't look" approach is based on the argument that PGT is not the community standard and is therefore, not required. However, PGT is a widely available diagnostic tool and the benefits of PGT are known and publicized and are increasingly a part of continuing education programs. As such, the issue is not necessarily the number of physicians using PGT, *i.e.*, community standard, but whether the test was available and could have prevented the bad outcome. By incorporating PGT into the plan of care, physicians can realize savings from potential liability in both time and money.

<u>Reducing Risk and Improving Patient Care</u>

High quality patient care should be the goal for all patient encounters. However, patient outcomes are also important because good patient outcomes typically correspond to a reduced likelihood of lawsuit or licensure scrutiny. Incorporating PGT as part of the patient treatment protocol improves the opportunity for good patient outcomes because it is a diagnostic test that provides information about the patient that is otherwise unknown. Specifically, the phenotype report from PGT identifies patients who are greater risk for bad medication outcomes or who may have unexpected results on a urine drug test ("UDT"). Once this risk is known, physicians can mitigate the risk by making dosing adjustments to avoid adverse reactions or avoid inappropriate discharges based on an unexpected UDT. In addition to reducing risk to patients, the information provided from PGT about the patient's ability to metabolize medications enables physicians to more accurately dose patients, improving the efficacy of prescribed medications.

Some physicians have argued against the need for PGT to assist with dosing decisions claiming that it is unnecessary because patients are typically started with a typical dose and titrated over time to achieve optimal dosing/quantity. This "trial and error" approach is costly and can negatively impact patient outcomes and, in the worst case, result in death. Moreover, taking an approach that intentionally ignores a diagnostic test that provides timely information to achieve a better outcome in favor of a gradual, prolonged experiment is nonsensical and would not be acceptable outside of medical practice.

Imagine you take your car to a mechanic for repair. Instead of running a diagnostic test that will tell the mechanic how to fix your car, he instead applies a standard treatment knowing that it will need to be adjusted over time. As a result, your mechanic tells you to bring the car back every month for adjustment until the repair is completed properly. It is absurd to think that anyone would have the patience to return to the mechanic repeated times for the mechanic to "titrate" the correct solution to the problem, particularly when there is a diagnostic test available that will enable the mechanic to properly address the problem during the initial visit. Unfortunately, the "trial and error" approach is considered "acceptable" by those who advocate for it, but differs from the mechanic example because the physician's plan could result in the death of the patient.

PGT can provide information that results in better patient care and as such, incorporating PGT into the patient's care protocol should be a routine practice. Federal health care reimbursement models continue to add more quality and performance measures, and Accountable Care Organizations and the outcomes they produce are increasing in prevalence. As a result, physicians will need to embrace technologies and resources such as PGT that decrease costs and risks to patients, increase patient safety and treatment efficacy, and provide better patient outcomes.