Overview of Project Results

We have found that delivering preemptive pharmacogenomic results to participating study providers leads to measurable benefits for providers and patients. We analyzed data comprised of more than 2,200 outpatient clinic visits over a 3-year period for 547 unique preemptively genotyped patients enrolled in our institutional implementation program. Of these evaluated visits, clinicians accessed the GPS 69% of the time, with providers being more likely to log in to the system at visits where medication changes were made (Odds Ratio (OR) = 1.6 [95% Confidence Interval [CI], 1.2-2.1], p < 0.0001). (They did not access GPS at some visits, for example, due to time constraints.)

Importantly, more than one-third of medications that patients were currently taking (at the time of the visits in question) were associated with pharmacogenomic information. We determined whether these patient-specific pharmacogenomic results influenced prescribing by analyzing medication change rates and found that both red and yellow light medications were changed more often than medications with no pharmacogenomic information.

The OR of a red light medication being changed was 26.2 (CI, 9.0-75.3) (p < 0.0001), while that of a yellow light drug was 2.4 (CI, 1.7-3.5) (p < 0.0001). Green light medications, on the other hand, were not changed significantly more often than medications without pharmacogenomic information, suggesting favorable genomic signals may have confirmed providers’ prescribing choices—a perhaps underappreciated aspect of pharmacogenomics.

Alongside analyzing provider behavior in response to pharmacogenomic results availability, we also studied patient perspectives through surveys and focus groups. We found that when providers considered pharmacogenomic results, patients perceived increased doctor-patient empathy and privacy, a better understanding of medical decision-making, and most significantly, a greater sense of personalized care from their providers.

Results from patient focus groups also showed that those who were previously genotyped were open-minded about the use of their pharmacogenomic results in the clinic. Regardless of whether patients had been genotyped, they expressed concerns about employment discrimination and insurance coverage based on pharmacogenomic results.

Taken together, we believe our results on patient perspectives represent vital considerations for implementation efforts, as patients are key stakeholders in widespread adoption of pharmacogenomic testing. Importantly, our efforts would not have been possible without early engagement and support from key institutional stakeholders, including institutional leadership laboratory personnel, the research informatics and hospital informatics teams, and the willing early-adopter physicians and patients.

Reimbursement Challenges

The last major challenge to wider adoption of pharmacogenomic testing is the currently limited scope of insurance reimbursement for germline pharmacogenomic tests. At this time, most major carriers cover only a handful of gene/drug pairs. Payors may be awaiting additional prospective data (including perhaps cost-effectiveness analyses) before deciding about expanded reimbursement for additional drugs and genes/variants. However, recent analogous decisions about panel-based “composite” tumor-based genomic approaches in the realm of oncology provide one illustration of how preemptive germline testing could be evaluated going forward.

Recently, the Food and Drug Administration (FDA) approved Foundation Medicine’s tumor genomic profiling test, FoundationOne CDx, which interrogates more than 300 somatic genes “preemptively” in one panel. Simultaneously, the Centers for Medicare and Medicaid Services...