Putting PGx into Practice

An interview with Bernard Esquivel, Chief Medical Officer, GenXys Health Care Systems

BERNARD ESQUIVEL is a practicing physician-scientist, senior executive, and international leader with in-depth expertise developing new markets, devising compelling value propositions, go-to-market strategies, and launching programs to fulfill organizational goals and objectives in the healthcare space. With training as a Clinical Immunologist, Allergies, and Medical Genetics specialist he also has 10+ years' experience in materializing biotech and health sciences ideas and concepts into clinically actionable solutions. Dr. Esquivel mobilized the local healthcare community to engage them in the practice of precision medicine by founding and presiding over the Latin American Association of Personalized Medicine (ALAMP). This organization now includes >500 members from 9 countries in Latin America, holds symposiums, provider workshops, and other educational outreach per year. Serving as Chief Medical Officer for several well-renowned global organizations, he has demonstrated his passion and advocacy for bringing precision medicine closer to patients.

Markets and Business Development

Q. You, Dr Esquivel, have unique experience in precision medicine based on your educational background, the global biotech exposure you had, and the opportunity to deploy different projects within it: from precision medicine clinics and molecular testing companies to multicenter studies. What lessons have you learned during that time? Or are the lessons specific to time and place?

A. It has been a fantastic journey that is not even close to its end. I can humbly state that I have learned a lot, but these things are key to success: find your passion and be driven by it; back up your commercial claims with robust, proven scientific evidence; don't forget what the users want; clinical actionability is crucial; patience is a great virtue; the right timing for going to market will impact the outcome; and most important, patient safety comes first.

Q. You recently joined GenXys, a notable player in pharmacogenomics (PGx)-informed precision prescribing/ decision support software. How have you used those lessons and your experience in your current role at GenXys to develop a strategy for introducing and developing new technologies and new services in existing and emerging markets?

A. I'm several weeks (as of this publication date) in at GenXys, but I have been following them for years because they are all about activating actionability and enabling the next generation of PGx usability.

These ideas have been embedded in the company since its creation. The founders have always kept clinical actionability in mind to benefit patients. Hence, this organization has taken the time to mature the concept before bringing this unique and holistic personalized prescribing solution to the world. Like everyone, I have heard the buzz about the GenXys solution's ability to support patients and health providers in the widespread use of PGx.

Q. What have you observed as barriers to the implementation of pharmacogenomics, here in the US as well as in other countries?

A. The most common "barriers" are the need for education and training around precision edicine as well as coverage/reimbursement. Coupled with this 'the pharmacogenomics in a silo' doesn't help. Physicians don't need to be geneticists, but they need the tools to enable them to seamlessly incorporate PGx in their evidence-based decision making at the point of care.

Q. Can you comment on the differences in reimbursement considerations in the US? What is the GenXys role is requesting and securing reimbursement for GenXys products and services?

A. Even though precision medicine has become a trend and elements of it are underway, it is still

a critical topic and the stakeholders involved still have a lot of work to do. Thus, GenXys is committed to collaborating and engaging with the industry to continue to help prove the care savings and other relevant milestones needed for full coverage and reimbursement. Even without direct reimbursement there is a positive ROI for the use of PGx. The problem is that if you are going to pay for a PGx test, then the results MUST be used. Typically, they are not being used because it is too difficult this is what the next generation of solutions like GenXys solves.

Q. How can precision medicine help address diversity and equity gaps – making new technologies available to underserved groups (e.g., by location or income)?

A. A good example is in fact PGx. Pharmacogenomics allows us to know how a patient may respond to some medications based on their genetic information. In many genes such as CYP2D6, the prevalence of different polymorphisms varies considerably across ethnic groups. Thus, we cannot use the same "test" for all the patients; we need to verify that the test we are using has the right allele coverage to make the correct recommendations and help the battle against health disparities. For example, Allopurinol is a medication used to treat Gout. The Han Chinese ethnic group is a significant population group in Vancouver for example, who carry the HLA-B*58:01 variant more often than other ethnic groups. People with this variant have a much higher risk of developing allopurinol induced SCARs.[1] So, a key question is: should all Han Chinese people who are diagnosed with Gout have a PGx test?

Precision Medicine/Precision Tools

Q. PGx is now making its way from research into clinical trials and clinical applications for patient treatment in physicians' practices. Has this been the case for hospital and healthcare systems generally or is take-up on case-by-case basis?

A. We are in the midst of an amazing time where clinical adoption is growing faster than ever. There is evidence behind pharmacogenomics regarding clinical validity and utility, which has been proven in research hospitals. This process has also brought to light and reinforced the challenges in its widespread adoption. Now is the time to focus on clinical actionability, cost-effectiveness, and proper implementation.

Q. Biomarkers from PGx and other sources provide the source for many assays – diagnostic, prognostic, predictive and therapeutic. How do you see your role at GenXys (and in general) about advancing biomarkers as indicators for drugs (e.g., CDx) and contraindications (e.g., for ADEs)?

A. Biomarkers such as in pharmacogenomics need to be considered as another piece of the puzzle. The ideal scenario is to combine them with other well-known datasets that impact how a patient may respond to a prescription such as age, weight, kidney and liver function, comorbidities and other diagnoses, drug-drug interaction, social determinants of health, and pharmacogenomics in an evidence-based, clinical guideline-oriented, and holistic way. That is the GenXys value proposition.

Q. Could you please provide background on Predictive Risk Scoring at GenXys? What factors go into the risk estimate? How is it used for assessing recommendations for physician support?

A. GenXys's predictive risk scoring capability is powered by our IdentifyPGx solution. This solution uses a population-based approach that informs the organisation/practice about the characteristics of the population and what proportions might be at risk. It is designed to help with the planning of a pharmacogenetic strategy and not individual patient care. It enables the organisation to determine the criteria (risk/condition/drug) to use to determine who to offer PGx testing to so that they have a clear idea of numbers and characteristics of those individuals. It also helps them have an idea of the potential return on investment (ROI). Some of the key factors that go into the risk estimate include those that are associated with adverse drug events, drugs with known drug-gene interactions, known drug-drug interactions, and other factors such as renal function and liver function.

Q. Interoperability has long been a requirement in IT driven systems. How do you see this capability informing the expansion and uptake of precision medicine in terms of making data and analysis more accessible across systems and platforms? What are the advantages (disadvantages) for GenXys? For users?

A. Speaking the same language has become a top priority in terms of implementation and adoption. GenXys is acutely aware of the need for interoperability. Being flexible during implementation, and finding ways to jump into our customer workflow, is one of our top goals. Some functional capabilities have been developed, such as: being platform-agnostic (the ability to digest any sort of validated genomic input); EHR, LIS (lab information systems), PMS (Pharmacy Management Systems), and Claims Management Systems integration; and developing ad hoc API's. In today's world, precision medicine approaches need to transcend the whole continuum of care from pharmacist, to family doctor, to specialist, to the fracture clinic at my favorite ski resort. Like everything, patients – the consumers – expect portability and access to their data, particularly when it is going to impact the treatment they receive. JoPM

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About GenXys

GenXys is revolutionizing healthcare with precision prescribing software and pharmacogenetics. Our mission is to improve drug safety, increase efficacy, and reduce healthcare costs.

GenXys provides the world's most comprehensive precision prescribing software to solve healthcare's most pressing challenges. Our precision prescribing software and pharmacogenetic solutions prevent adverse drug reactions, a leading cause of death in developed countries, and personalize drug selection to increase drug efficacy. Powering every prescription with our software improves medication safety, increases drug efficacy and reduces healthcare costs.

See also TreatGx, ReviewGx, IdentifyPGx, ConvertPGx, TreatGxPlus at https://www.genxys.com/content/

References

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