



Health Services Advisory Council

Minutes — January 14, 2016
3:00 – 5:00 p.m.
DHS Andersen Building, St Paul

Members Present

Timothy Sielaff (chair), Don Brunquell, Amelia Burgess, Howard Fink, Andrea Hillerud, Patrick Irvine, Chris Johnson, Tamiko Morgan, Jeff Schiff (non-voting), Cedric Skillon

Members Absent

Jim Miner

DHS Staff Present

Ellie Garrett, Dave Hoang, Robert Lloyd, Cindy Marihart, Sarah Rinn

Others Present

Melissa Geyer (Assurex Health), Tamara Graziano (psychiatric nurse) Jim Pollard (Assurex Health), Amber Soukkala (University of Minnesota), Joel Winner (Assurex Health), Kristine Willey (Assurex Health)

I. Welcome, introductions, updates and minutes

Timothy Sielaff welcomed everyone, and introductions were made around the room. **On motion made and seconded, the members voted unanimously to approve the November meeting minutes with no corrections.**

Jeff Schiff provided brief updates from DHS: Governor Dayton appointed Emily Johnson Piper as the new Commissioner of Human Services. The Opioid Prescribing Work Group (OPWG) is meeting monthly, having convened for the first time in November. Chris Johnson represents HSAC on the OPWG. The legislative session will be short this year, since it's a bonding and not a budget year. Work has begun to plan for the 2017 session.

II. HSAC membership update

Ellie Garrett introduced Chris Johnson, who was attending his first HSAC meeting in person. (He participated by phone in November.) HSAC has two vacancies, strong candidates for which have been identified.

III. Principles for prioritizing existing quality measures

Robert Lloyd summarized ongoing work at DHS to reduce the burden of quality measurement and prioritize measures that better reflect health outcomes and health status. A copy of his presentation is available upon request from [HSAC staff](#). The proposal builds on the [Institute of Medicine's *Vital Signs*](#) report as a basis for rethinking quality measurement. Schiff observed that the challenge is to bridge health care and population or public health. Members discussed the *Vital Signs* report's domains and elements. A member asked for context about quality measures. Perspectives about a measure's utility will vary depending on whether it's being used for quality improvement or accountability, for example. Another member observed that some of the higher level measures, like injury and violence are too broad; a more finely tuned approach would discern between different causes and interventions. Another member observed that measurement is costly, and if measurement results are not well used, then those dollars that could otherwise be directed to patient care are wasted.

A member discussed measurement of value (expressed as cost and quality combined) and of equity. Another asked about resources to act on problems identified through measurement and of connecting measurement to outcomes. Discussion concluded, and the chair opened the floor up to public comments. There were no comments offered regarding this topic.

IV. Pharmacogenetic testing and GeneSight Psychotropic

Garrett summarized the federal regulatory environment for pharmacogenetic testing and the published studies pertaining to GeneSight Psychotropic. According to the National Human Genome Research Institute (NHGRI), which is part of the National Institutes of Health, these tests are largely unregulated at the federal level. NHGRI suggests evaluating a genetic test's usefulness based on three criteria:

- Is the test accurate and reliable? (Analytical validity)
- Is the test result medically meaningful? (Clinical validity)
- Does the test improve healthcare? (Clinical utility)

The GeneSight product analyzes various genes and then groups drugs for the patient's individual genetic profile into three categories according to a proprietary algorithm:

- Green: use as directed
- Yellow: use with caution
- Red: use with increased caution and with more frequent monitoring

Garrett reported that the scientific evidence supporting GeneSight Psychotropic's usefulness for the treatment of depression or major depression is scant and flawed:

- The GeneSight product being marketed today is not the one that was studied. Both the number of genes and drugs have expanded since the studies were performed.
- All studies were authored or co-authored and funded by the manufacturer or patent-holder and have high risk of bias due both to study design and to unmanaged conflicts of interest.
- The manufacturer's claims about effectiveness hinge on two, small open-label studies and one small, partially blinded randomized controlled trial (an RCT with statistically insignificant results) and a meta-analysis of same. The published articles call for more study.

- The manufacturer’s claims about cost-effectiveness rely either on the small effectiveness studies mentioned above or two studies that are otherwise limited: (1) in one case, a retrospective analysis of one psychiatrist’s practice; and (2) an examination of pharmacy costs alone that ignores the cost of the intervention or of other health care utilization.

A copy of Garrett’s presentation is available upon request from [HSAC staff](#). Members asked several questions concerning the GeneSight studies’ methodology and results. In response to questions, Garrett or Assurex representatives clarified several points, including;

- The randomized controlled trial reported in Winner 2013 was not blinded to the treating physician/prescriber. It was blinded to the patient and investigator.
- The red/yellow/green categories do not purport to predict which drugs work for what patients, but are designed to suggest whether (and if so, the degree to which) more caution or monitoring would be appropriate.
- Joel Winner, an Assurex Health representative and a psychiatrist, explained that drugs prescribed for depression are metabolized by multiple enzymes. The GeneSight approach takes into account the complex response of multiple genes. Winner disclosed that he is Assurex Health’s medical director and as such owns stock in the company.
- Winner explained how control patients were matched for propensity in the drug cost study. Savings were reported for one year of drug costs. The cost of the intervention (GeneSight test) was not reflected. A member commented that one cannot extrapolate based on the study that cost savings would continue into later years.
- Another member questioned whether the studies (or underlying studies) established whether the genotypes in question really predicted phenotypic action.

In response to a question, Schiff clarified that DHS is being requested to cover GeneSight, and there are more such tests on the horizon. Discussion ensued.

The chair opened the floor up for public comments, and Winner drew the council’s attention to several PowerPoint slides. A copy of Winner’s full PowerPoint presentation, which he did not have time to present in whole, is available from [HSAC staff](#). Among other things, he stated that the Food and Drug Administration (FDA) includes pharmacogenomic language in the package inserts for 29 of the 38 medications on the GeneSight Psychotropic test. Questions from members continued during his presentation. He clarified that GeneSight is intended to be used along with medical history, not to supplant patient history and other relevant treatment information. He also clarified that it is for treatment resistant depression, and has not yet been studied in treatment naïve patients. In response to a question, he stated that the Assurex lab provides two-day turnaround for test results.

A member pointed out that achieving a 3-point difference on a 60-point depression scale is not meaningful. Winner drew the council’s attention to his slide showing the current standard of care, with a quote from the American Psychiatric Association, “The effectiveness of antidepressant medications is generally comparable between classes and within classes of medications.” The slide also showed the shrinking return in terms of lowered treatment responses and increased side effects for patients undergoing numerous drug trials.

Tammy Graziano, a psychiatric nurse practitioner from Advanced Practice Solutions and working with Ramsey County Jails, Meridian and NorthPoint, offered public comment. She stated that she has used GeneSight for a year, and her patients have had favorable outcomes. Patients have a voice with this tool, and can see how their genetic profile informs her prescribing practice. At first she used it only with

patients who were not complying with their drug therapy. Now she uses it for every initial diagnostic evaluation, and explains with each patient how their genetic profile guides her prescribing.

Jim Pollard from Assurex clarified that Assurex is currently providing the test at no cost for Medicaid and other low-income patients lacking coverage for the test, but will have to begin billing for the test in the future. Assurex has also obtained a favorable Medicare local coverage decision, the only neurological pharmacogenetic test to have such standing. Pollard stated that he appreciated HSAC's transparency and welcomed input from Minnesota's Medicaid program about what kind of data it needs to support coverage.

A member asked for information about the study designs of the trials currently in progress. Another member asked about the diversity of the populations being studied. Garrett agreed to circulate information about the research protocols.

The chair asked members to remember that its discussions of GeneSight are as a case study, offering an opportunity to derive principles on which new pharmacogenetic tests can be considered.

The meeting was adjourned.