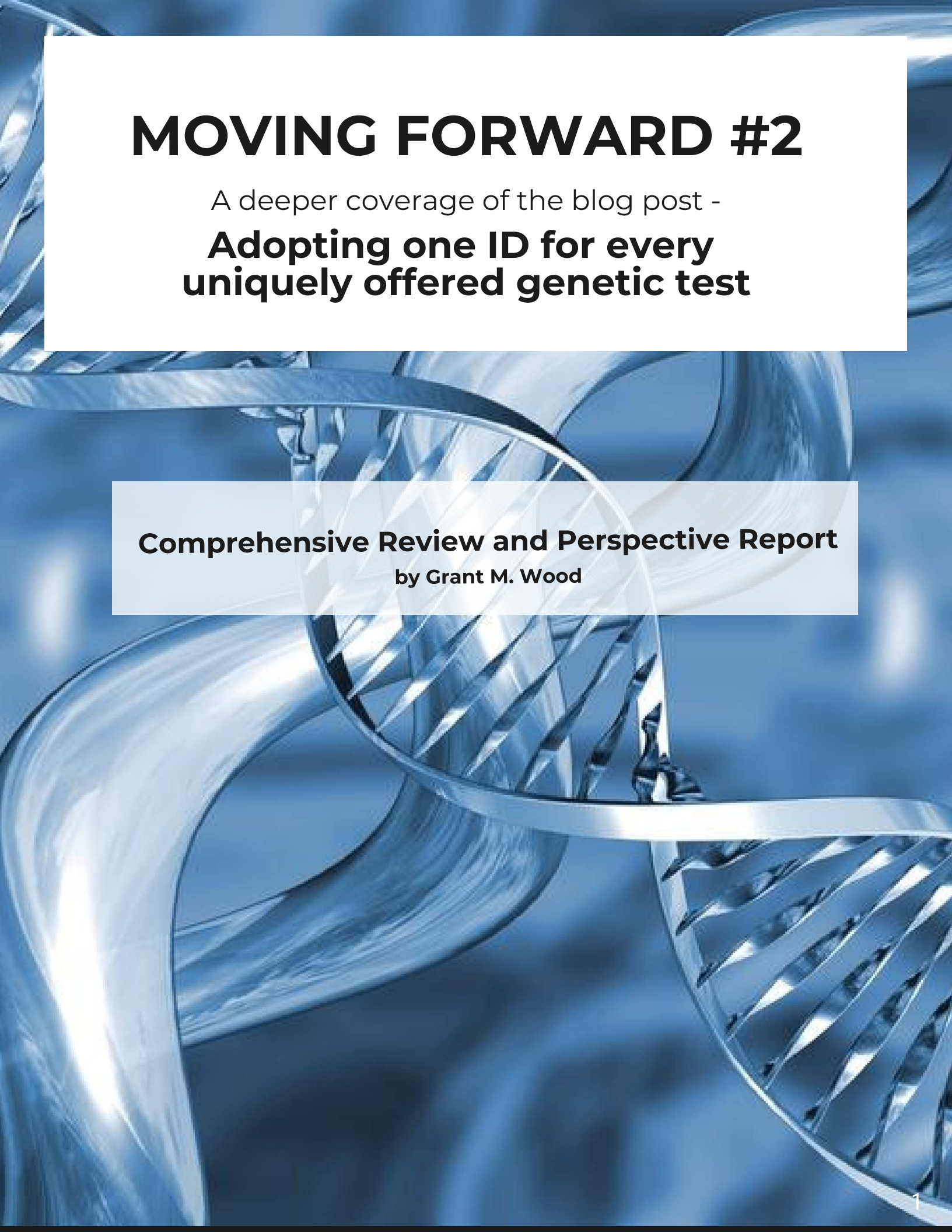
MOVING FORWARD #2

A deeper coverage of the blog post -

Adopting one ID for every uniquely offered genetic test



Comprehensive Review and Perspective Report

by Grant M. Wood

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Introduction

Each year there has been an increase in the number of healthcare providers offering genetic testing services, including hospitals, private practices, academic medical centers, direct-to-consumer commercial companies, and other entities.

While this is good news for patients seeking genetic-based care, for the care delivery system it creates challenges with regard to standardizing terminology used to describe those genetic tests.

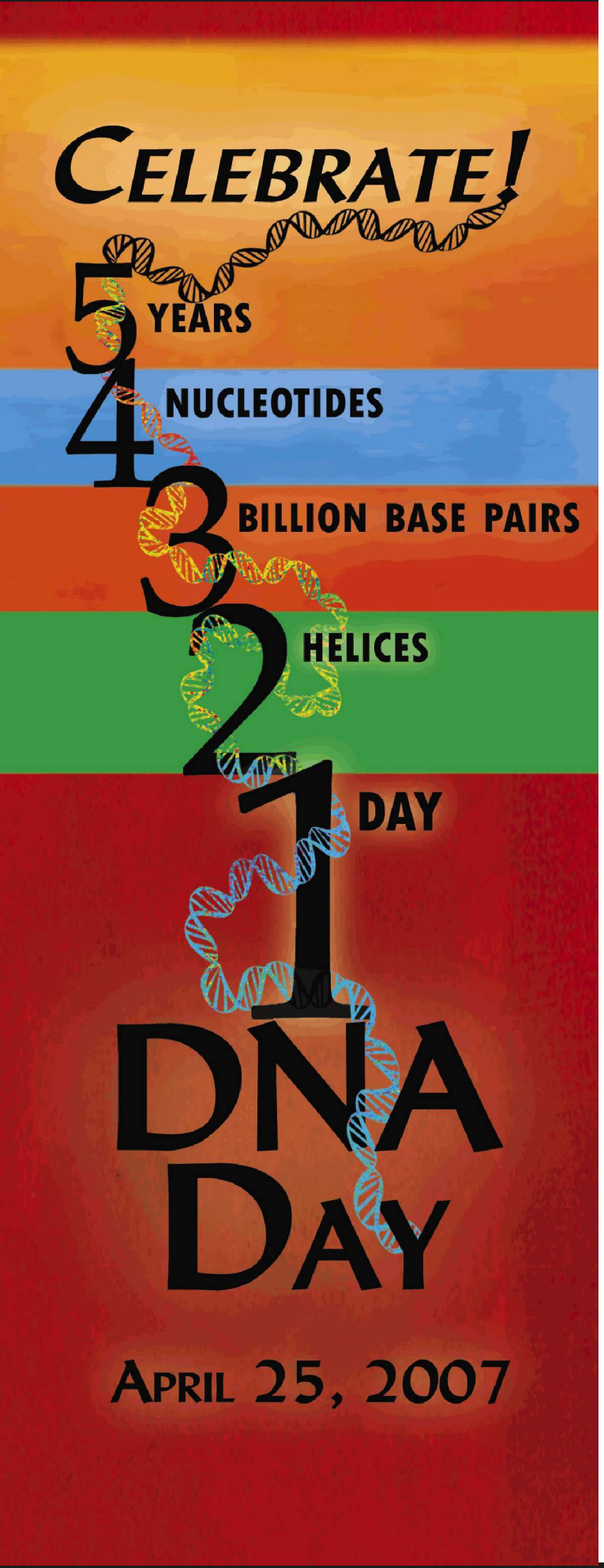
There are currently no widely accepted standards for defining what constitutes a “genetic test”, or for describing its results - which may differ depending on several factors such as the type of test being conducted and what information it provides about your risk factors for developing certain diseases or conditions. The current lack of standardized terminology leads to potential confusion among clinicians when ordering tests and laboratories when performing them.

What is needed

This proliferation of tests has created a need for a common identification system to ease communications between ordering clinicians and laboratories performing genetic testing on patient specimens. To achieve accurate information exchange, it is important that all ordering clinicians and laboratories be able to reference the same standard when talking about specific genetic tests.

The second need is to provide consistent information regarding each test's performance characteristics: what types of clinical situations are appropriate for its use; how long results can be expected; what interpretations may be considered clinically useful; any known limitations in its application; whether the test is being offered in research studies or as part of routine care; and so forth.

The smartest conclusion is adopting a data standard using a single identification code for every uniquely offered genetic test is a crucial step towards improving the accuracy and efficiency of the genetic testing process in healthcare. With the increasing demand for personalized medicine and the growing number of genetic tests being offered, it is important to have a standardized system in place to ensure that test results can be accurately interpreted and effectively used in patient care. In this post, we will explore the benefits of using a single identification code for genetic tests, the challenges involved in implementing this standard, and some best practices for achieving successful adoption.



My experience

Looking back more than 10 years, I was trying to perform a utilization analysis on clinical genetic testing with my employer, a large integrated healthcare system.

The problem was that our lab results database used either generic or high-level codes for all of the genetic tests. Most tests were coded as "MSO" (miscellaneous send outs), while others had high-level codes like "CFMUT" for any cystic fibrosis mutation test or "FRXDNA" for any Fragile X Syndrome test.

These codes could not distinguish which lab developed the test, which sequencing methods were used, the specific DNA coverage details, or the possible differences in the sensitivity and specificity between similar tests. We could not determine the clinical effectiveness of each test because we could not clearly differentiate between them.

Today, genetic tests become more complicated and unique as the complexity of the test increases.

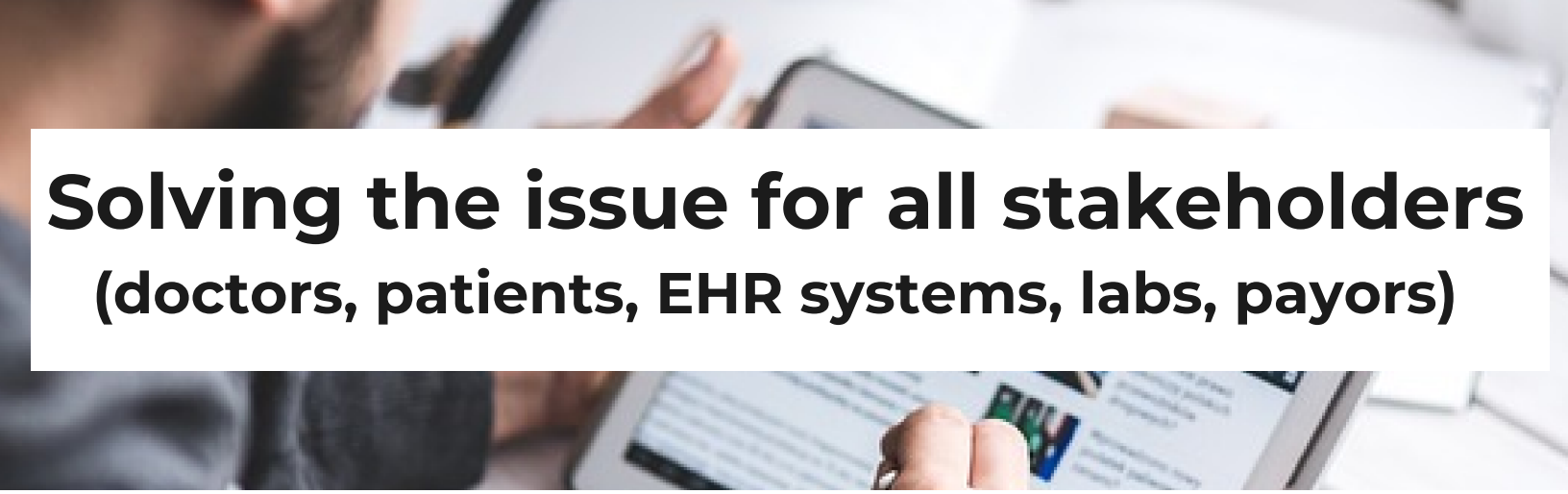
There are over 175,000 genetic testing products, ranging from single gene mutation tests and microarrays to multi-gene to whole exome and whole genome assays, and a large and growing number of them have reasonable evidence for clinical utility.

Compounding this issue was the fact that ICD-10-CM codes do not exist for many genetic mutations that are deleterious for the disease, especially in the rare disease area. Most of the time, we were not able to count how many patients there were with specific genetic disorders. (See the article on GenomeWeb about this problem. Available only through their Premium subscription.)

Call to Action

Concert Genetics has a solution, the Genetic Testing Unit (GTU). The GTU is a five-digit alphanumeric character sequence for every uniquely marketed test, even after the test is no longer available. I propose that the industry adopt this coding system as a standard today - to move forward.

The industry's use of the GTU identifier coding system will complement the use of CPT and HCPCS procedure codes, eliminate claim field ambiguity, reduce administrative work and costs, and most importantly, help expand patient access to genetic testing and precision therapies. If you want to join this Call-to-Action, send ideas, efforts, and results to moveforward@genomics.network.



Solving the issue for all stakeholders
(doctors, patients, EHR systems, labs, payors)

Here are some of the cross-stakeholder issues that adoption of the GTU identifier could solve:

- With the ability to search and compare similar tests from different labs, determine if the test is clinically appropriate for the patient.
- The unique genetic test ID, when linked to details about the test, could be key to developing advanced genetics-based clinical decision support (CDS).
- Help ordering healthcare providers navigate and understand the significant differences in genetic test coverage between health plans.
- Help standardize pre-auth and billing policies for genetic testing among plans.
- Advance the quality and volume of genetic test assessments and medical necessity policies.

Opportunities for new EHR technology applications will emerge, such as CDS-based genetic and genomic test ordering guidance, e.g., checking that you have the appropriate clinical indication or family health history when a test is ordered. Then the EHR could improve the ability to use the results clinically in diagnosis, therapy, and further screening decisions. And when the test results contain variants of unknown significance, what is interpreted as unknown and insignificant today may be known and significant tomorrow. We need the system functionality to quickly update past test results in the EHR with the new knowledge and act upon it clinically if necessary.

Laboratory issues and data standardization

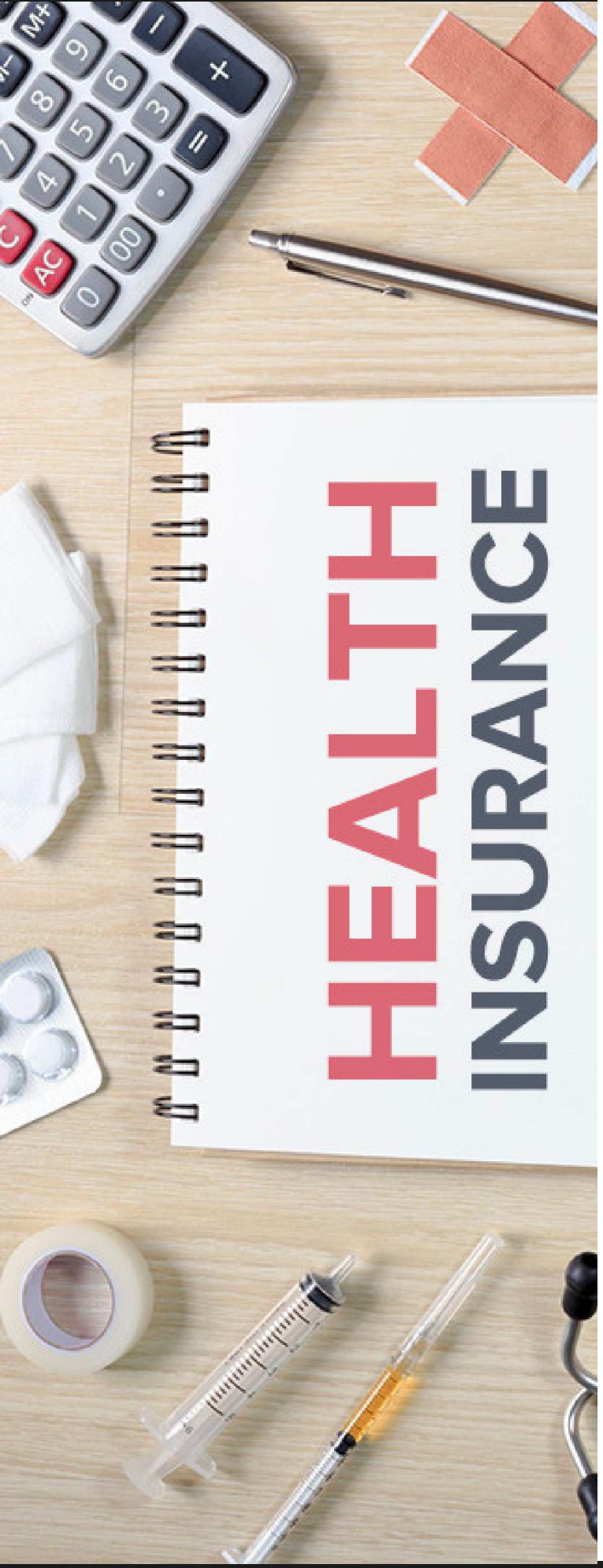
Data standardization is important because it eliminates the potential for confusion among clinicians, laboratories, and patients when ordering and reviewing tests.

Without a standardized way to identify genetic tests offered by a laboratory, clinicians may use different terminology than the lab uses to identify these tests in order to prescribe them. This leads to possible uncertainty on both ends of the communication sequence.

Labs compete for customers when they develop similar but distinctive tests. Even with similar tests, this creates differences in the meta-data, quality of the read, bioinformatics approach, methodology of the tests, and reference sequences used for the interpretation, which adds to the uniqueness of each test. This is an area that is changing rapidly, with no coding standards being used to identify each unique test.

Laboratories often have multiple processes for identifying each genetic test offered, depending on how they want their customers (clinicians) or other stakeholders (patients) to interact with that information. For instance, a certain gene-disease pair may be linked to more than one numeric identifier in one lab's system but only one in another lab's system.

Furthermore, some laboratories offer more than one kind of test for several genes at once, while others offer only one kind of test per gene, and still others offer just an overview of all available tests across many genes (e.g., exome profiling). Even more ambiguously, there might be two distinct types of tests available for any given gene-disease pairing. As an example of this, there is whole exome sequencing versus germline mutation scanning.



Insurance plan issues

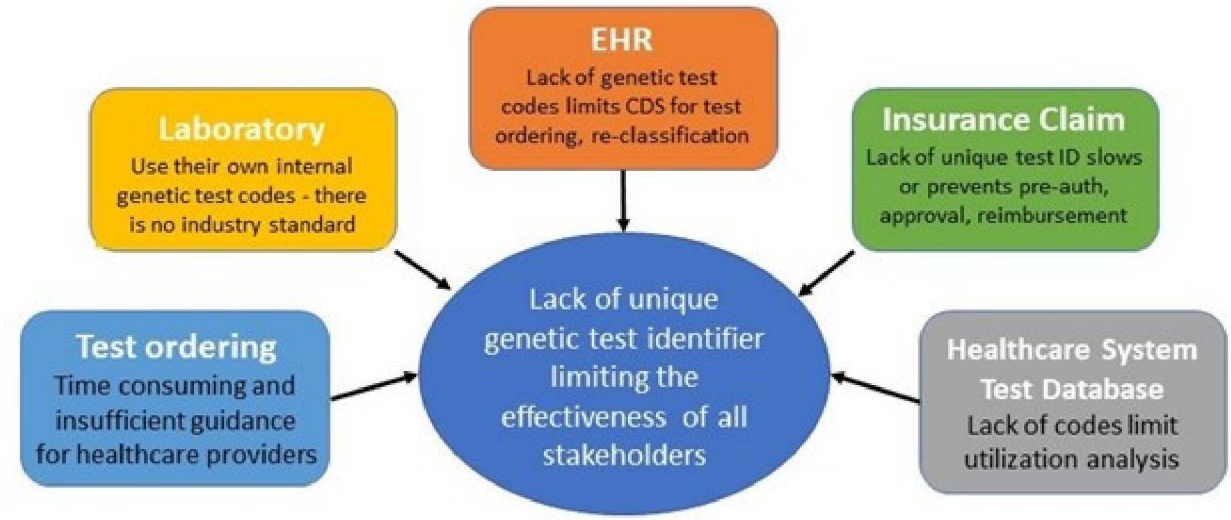
When an insurance claim includes a genetic test, the Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) have approx. 670 codes to represent the 175,000 tests.

A widely used identifier would solve problems with efficiency by getting rid of uncertainty, which leads to manual reviews, wrong payments, or denial of genetic testing services on the front end and makes it hard to figure out the economic and clinical value of genetic testing through data analysis on the back end.

Then there is this continuing battle over coverage and reimbursement for genetic and genomic testing versus their proven clinical utility, both today and over the patient's lifetime. The healthcare delivery systems want consistency in coverage policies among the differing plans. I have a survey seeking to understand some of these business concerns. See the 2-minute survey here.

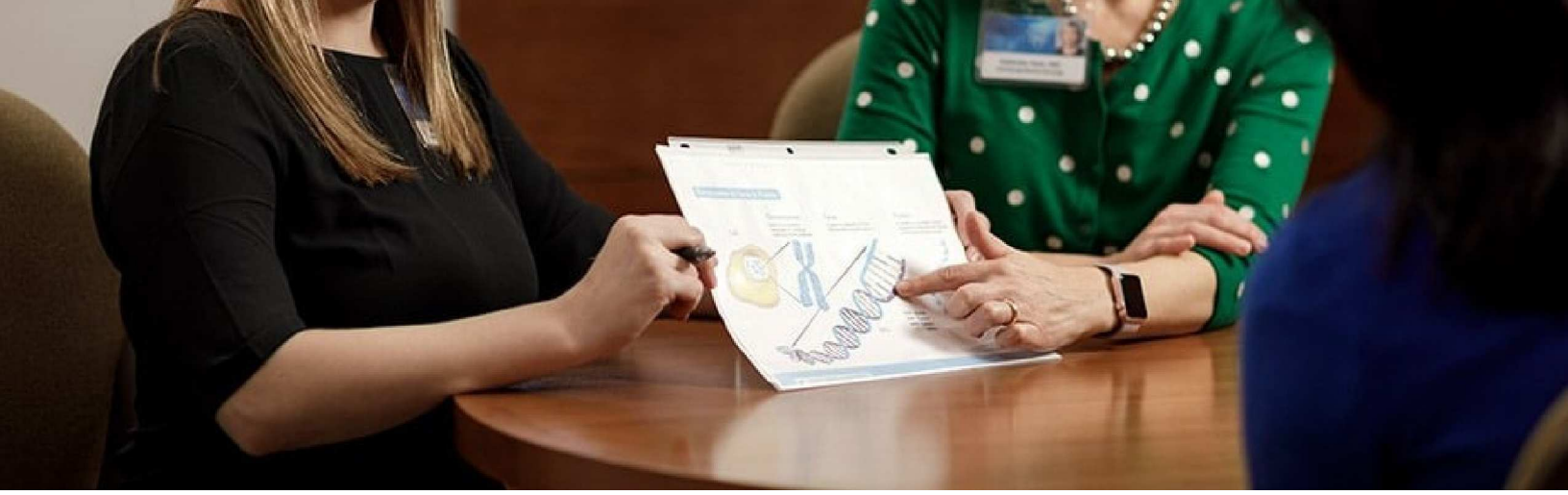
Benefits of a unique identification code

Using a single identification code for every uniquely offered genetic test has several benefits. First and foremost, it ensures that test results can be accurately interpreted and effectively used in patient care.



Without a standardized system, it can be difficult for healthcare providers to accurately understand the meaning of test results and how they should be used in treatment decisions. This can lead to misdiagnosis and inappropriate treatment, which can have serious consequences for patients.

In addition to improving patient care, using a single identification code for genetic tests can also improve the efficiency of genetic testing. It allows for better tracking and reporting of test results, which can help identify trends and patterns that may be useful in research and development. It can also help to reduce the risk of errors and mistakes, as there is less confusion about which test is being referred to.



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The GTU Adoption Outlook

Concert Genetics has made the GTU available for use royalty-free, and will only require a license for derivative works. The significant evidence proving the validity of this proposal encompasses the following:

- All key requirements and criteria for a genetic test ID are met by the GTU standard.
- The GTU is compatible with existing integration methods and systems.
- The GTU does not conflict with other classification and identification systems already in use.
- IDs are assigned as soon as new tests are released to the public.
- In addition, six health plans have already requested that GTU codes be added to the Procedure Description element (837P SV101-7) of their published payment policies. Four more health plans will join them in the next few months, with many others starting the adoption process.

Best practices for successful adoption

To successfully use a single identification code for genetic tests, it is important to follow a few best practices:

1. Involve all relevant stakeholders in the planning and implementation process, including test manufacturers, laboratories, health insurance payers, healthcare providers, and regulatory agencies. This will help to ensure that the needs and concerns of all parties are taken into account.
2. Communicate clearly and transparently about the purpose and benefits of a single identification code system, as well as any potential risks or concerns. This will help to build trust and ensure that all parties are on board with the adoption process.
3. The coding system must be flexible and adaptable enough to accommodate the rapid pace of technological and scientific advances in the field of genetics. This could mean setting up a way to check the codes regularly and update them as needed.
4. Establish a central authority or repository to manage the codes and ensure their accuracy and consistency. This organization should have the resources and expertise to handle the responsibilities of this role effectively. I argue that the **GTU coding system from Concert Genetics** fits these requirements.
5. The new standard should be adopted by all relevant stakeholders involved in creating, offering, utilizing, and reimbursing genetic testing services. It also needs to be implemented by hospitals' LISs and other electronic health record (EHR) systems in order for them to recognize the ID numbers assigned to each test.

Conclusion - Opportunities for Moving Forward

Approach Your Messaging with a New Look

A genetic test identifier standard for the industry will solve many authorization, billing, and reimbursement problems. Such an identifier will support the clinician in quickly finding and reviewing equivalent, high-quality genetic tests that have reimbursable coverage.

Currently, healthcare providers and labs are missing the benefit of shared economic analysis of clinical genetic testing performed in partnership with insurers. Opportunities for innovative collaborations between these groups are not being realized.

The time for endless contemplation and indecision on this issue is over. It's time to implement the GTU identifier and move forward. For those who agree, report back to me on your progress, and I will cover your organizational achievements in this blog.

Labs and health plans that want to incorporate the GTU into their billing systems and practices should email info@concertgenetics.com.

Contact Grant M. Wood at moveforward@genomics.network

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