REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 03-A-23

Subject: Regulation and Control of Self-Service Labs

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Referred to: Reference Committee E

At the 2022 Annual Meeting of the American Medical Association (AMA), the House of Delegates adopted Policy D-260.992, "Regulation and Control of Self-Service Labs." That directive called for a study into "patient-directed self-service testing, including the accreditation and licensing of laboratories that sell self-ordered tests and physician liability related to non-physician-ordered tests". This report serves as the Council on Science and Public Health's (CSAPH) findings and recommendations regarding self-service testing, also known as direct access testing (DAT) or direct-to-consumer (DTC) testing. The Council has previously studied DTC genetic testing which shares many issues with DAT. For the purposes of this report, DAT refers solely to non-genetic, non-imaging based diagnostic testing.

METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "direct access testing", "self-service laboratory", "direct to consumer laboratory", and "self-service laboratory AND liability". Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

BACKGROUND

Patient-directed testing has existed in the United States for decades, such as over-the-counter glucose testing kits available since the early 1980s. Currently, pharmacies sell a variety of at-home tests for pregnancy, illicit drug use, or other biomarkers. However, starting in the late 2010s, diagnostic companies began to offer a compilation of blood-based DATs such as hormone panels, electrolytes, heavy metal screening, metabolic panels, and prostate specific antigen (PSA). According to one estimate, the market for DAT in the United States currently exceeds $350 million per year, up from just $15 million per year in 2010.[1] Another source estimates that the DTC genetic and DAT lab services markets combined will exceed $2.4 billion per year by 2025.[2] For the purposes of this report, DAT will refer to medical tests that are not available as over-the-counter kits and are performed by a laboratory after being purchased by an individual without a prescription.

The DAT business model removes the health care professional, often the primary care physician, from the care decision-making and allows an individual to directly purchase their test from the laboratory. Overall, there is limited literature on DAT, the model, and outcomes for patients and their care. According to the Frequently Asked Questions webpage of one DAT company, orders for these tests are provided by a licensed clinician upon demand, but these tests are not reimbursed by insurance as they are not the treating health care professional and they do not provide CPT codes.[3]

While the process may vary from company to company, they generally follow similar steps. First, a patient is presented with a menu of available testing options. They then select the test(s) they would like performed, and then pay up-front for the test. A licensed clinician then orders the test, which the companies claim does not constitute a patient-physician relationship. The patient then visits a nearby facility for their sample(s) to be taken, and they receive their results within a few days. Results are often reported in the same manner as they would from a prescribed test in the usual course of care– a single value with solely the reference range as context. Unlike tests that come from a prescribing physician within a health-system, DAT companies do not provide any diagnostic assessment, counseling, or guidance on laboratory results. Patients are encouraged to share their results with their physicians, but it is unclear if or how any DAT facilities enter results into the electronic medical record or otherwise to alert a health care professional that a test has been performed.

DISCUSSION

Patient Safety

The most obvious concern around DAT is patient safety. Assuming the patient identifies an appropriate test to measure the biomarker of interest, patients often receive a single numerical value and a reference range for their test results with no additional description or suggested next steps. However, interpreting medical tests is more than simply seeing if a number is within the reference range. Physicians have years of training and experience to incorporate the quantitative information of medical tests with the qualitative information collected from the patient, including past medical history or signs and symptoms. Take for example the measurement of thyroid stimulating hormone (TSH), which typically has a reference range listed of 1 to 4.5 mlU/L, depending on the assay. A non-trained individual may receive a result of 4.3 mlU/L, see that it is within the provided reference range, and assume they have healthy thyroid function. However, a trained physician may recognize that in combination with presenting symptoms or other risk factors, that this individual may have early hypothyroidism and can begin intervention.[4]

Risk assessment is a critical factor for interpreting and acting upon medical test results, but it is also a key consideration for prescribing the test in the first place. For example, for PSA screening the USPSTF recommends a shared decision-making model, in which men aged 55 to 69 should be informed of the potential risks and benefits of PSA screening before making the decision with their physician.[5] PSA levels could be elevated from several non-cancer sources, such as benign prostatic hyperplasia or prostatitis, and that the risk of dying from prostate cancer was approximately 2.5 percent. Studies have found that approximately 80 percent of men who pursued aggressive clinical action such as brachytherapy due to elevated PSA levels experienced erectile dysfunction or incontinence as a result of treatment.[6] In recommending a screening one needs to consider the risks of false positives and over-diagnosis of benign, non-fatal prostate cancers outweighed that may outweigh benefits of early detection. USPSTF has found that PSA testing outside of a very specific risk category offers poor or even negative value to the patient.[7] This crucial risk-benefit analysis and discussion is missing when an individual can simply order a PSA test from a DAT website and may lead to unwanted outcomes. DAT companies do not follow any clinical guidelines for any test provided. They do not limit test offerings to those in the appropriate risk categories.

Legal Landscape

While the definition varies from state to state, the practice of medicine is typically defined as diagnosing, treating, or advising a patient on their symptoms or disease. It appears that DAT

companies are pursuing a loophole – if they explicitly do not advise a patient on what their test results mean, or use a biomarker to diagnose, they contend it is not practicing medicine. Currently 37 states allow DAT with varying levels of restriction. It should be noted that depending on the state, DAT companies might utilize a dentist, nurse practitioner, physician assistant, naturopathic doctor, licensed acupuncturist, or chiropractor to order tests.

There are also concerns about the duty of the physician when a patient presents with DAT results and requests their physician take clinical action. While the Council does not intend to offer clinical guidance, it cannot identify any scenario in which the action by the physician, if they choose to act at all, can be anything but re-ordering the test through appropriate channels. This is especially true in instances where the patient may have ordered a test the physician is inexperienced with – how can they be expected to act upon, and be liable for, a test they would not have ordered themselves? Current AMA policy and the Code of Medical Ethics regarding direct-to-consumer diagnostic imaging services states that any physician ordering a test is the responsible party for diagnosis and subsequent patient counseling.[8]

Finally, there are also concerns about the regulations of the laboratories performing the tests. There are two main ways in which clinical testing is regulated in the United States. First, if a test is fully self-contained (ie, a test kit), then it is reviewed for medical claims by the Food and Drug Administration (FDA) as an in vitro medical device. For all other medical testing, such as laboratory developed tests, laboratories are regulated, inspected, and certified by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvements Amendment (CLIA). The FDA categorizes laboratory tests based on complexity, which CMS then uses to develop regulations. Depending on the categorization of test complexity, CLIA may require quality standards for facility administration, laboratory systems, personnel qualifications, quality assessment, and quality control. CLIA certification is provided by CMS-approved accrediting bodies, such as the Joint Commission or the College of American Pathologists. Studies have found that the introduction of CLIA resulted in an increase in laboratory quality and customer satisfaction.[9]

There have been reports that some companies offering DAT skirt the CLIA certification process by claiming that since they only provide a context-free biomarker value, they are providing "health information" rather than a medical test.[10] Ensuring that these tests are performed in CLIA-certified laboratories is critical for maintaining the accuracy of the results while also making sure patients' samples and data are secure and stored appropriately.

Examining the Appeal

When assessing issues of DAT regulations, it is also important to understand the use-cases and surrounding ecosystem that has caused the market for DATs to flourish. DAT marketing often emphasizes a few key points: it is faster, the cost is upfront and known (ie, there is no unknown co-pay that will be administered later), and that an individual will be able to take control over their health. The first two claims are interconnected and point to the role health insurance companies play in reimbursement for testing. For example, studies have shown that when individuals enroll in a high deductible insurance plan, they are approximately 10 percent less likely to receive laboratory tests due to the financial disincentive.[11] It is also important to recognize that an insurance provider may require prior authorization, and then ultimately decline coverage, for outpatient laboratory testing which adds significant delays and cost uncertainty for a patient.

Additionally, there are several tests offered by DAT companies for conditions which unfortunately carry high levels of social stigma – particularly infectious diseases such as sexually transmitted

infections or hepatitis. In these instances, availability of a test which can be ordered online and without an uncomfortable conversation with their physician may be attractive to many patients. Tests for influenza or other respiratory viruses that can be ordered for home sample collection may also reduce the risk of transmission in a hospital or clinic setting. However, those instances in which DATs may be an appealing option further underscore the need for ensuring DAT facilities are CLIA-certified and responsible for the appropriate patient counseling on result interpretation and any necessary lifestyle changes.

Finally, DATs are often marketed to the individual who is seeking to better understand and control their health. For example, DAT companies may offer cholesterol panel testing, which would be appealing to someone who has changed their diet or exercise routine and is eager to see results. While those goals should be applauded, there are multiple risks associated with this approach. First, if the test is inaccurate, the individual will be given a false understanding of changes in their health. Second, the individual may not properly understand the time it may take for their changes to have an impact on a clinical biomarker, nor may they appreciate the healthy fluctuation the biomarker levels may have from day-to-day, or the size of impact their lifestyle changes may have on the biomarker. In some instances, an individual could discontinue medication or other treatments if they are given inaccurate test results devoid of context. Again, this highlights the critical importance of physician counseling in health management, as none of this information is currently communicated to patients utilizing DAT companies.

CONCLUSION

In a system of complex insurance reimbursement and high out-of-pocket plans, DATs may appear appealing for patients. However, current DAT practices appear to skirt regulatory requirements, could easily be misinterpreted by patients, and lack appropriate diagnostic and counseling practices by a physician. Potential utilization of DAT may be warranted in the realm of infectious disease when immediate testing would be beneficial for public health; however, test results should still be carefully communicated to the patient and monitored by a physician who is responsible for the patient's care.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following recommendations be adopted, and the remainder of the report be filed:

1. Direct access testing, in which patients may order a diagnostic laboratory test on demand, should only be provided by teams which are physician-led, and performed in facilities that are CLIA-certified.

2. Health care professionals who offer direct access testing services, for which a patient does not have a referral, recognize that agreeing to perform direct-to-consumer testing on request:
    a. establishes a patient relationship, with all the ethical and professional obligations such relationship entails; and
    b. assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Health care professionals may choose to refer the patient for post-test counseling to an appropriate provider who accepts the patient, but they maintain ethical and professional responsibility until the patient has been seen by that provider; and

shall report all required findings to relevant oversight entities, such as state public health agencies, even if the patient and the laboratory are not co-localized in the same jurisdiction. (New HOD Policy)

3. That Policy H-480.941, "Direct-to-Consumer Laboratory Testing," calling for regulation of direct-to-consumer testing and education of patients of risks and benefits, be reaffirmed. (Reaffirmation of Current AMA Policy)

Fiscal Note: less than $1,000

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