Direct-to-Consumer Disease Screening with Finger-Stick Testing:
Online Patient Safety Risks
Kimberly M. Lovett1,2,3,4* and Bryan A. Liang3,4,5

The direct-to-consumer (DTC) medical industry (i.e., medical testing and treatment outside of physician oversight) is growing rapidly as the Internet becomes more accessible globally. As several studies have highlighted, this industry offers unproven medical testing, provides testing for unapproved indications, and uses suspect advertising claims (1–5). Furthermore, given the prevalence of illicit pharmaceutical marketing (6), consumers are confronted with systemic online self-diagnosis and self-treatment risks that have emerged as a global patient safety and public health issue.

One particularly troubling practice DTC companies commonly use is finger-stick (capillary blood) testing for disease screening and diagnosis. Although useful in some clinical point-of-care applications, finger-stick testing carries substantial risks when offered to the consumer for screening, diagnosis, or disease monitoring without professional oversight. Although other nonvenipuncture alternative-site testing carries many of the same risks, we focus specifically on the dangers of finger-stick testing because of its widespread use by DTC vendors. Because of the present situation and the unique patient safety risks we outline below (e.g., low diagnostic sensitivity, strip factors, logistics of testing), creating a regulatory framework for finger-stick testing could ensure legitimate evidence-based applications, patient safety protections, and responsible advertising that accurately reflects risks and utility.

Unauthorized Practice of Medicine

Offering DTC finger-stick medical testing in conjunction with information suggesting potentially abnormal results may in fact constitute unauthorized medical practice. According to the Federation of State Medical Boards, medical practice includes “offering or undertaking to prevent or diagnose . . . by any means . . . or devices any disease, illness, pain, . . . or abnormal physical condition of any person . . . .” (7). Many DTC medical-testing companies seem to fit squarely within this definition.

Indeed, a simple Google search for “home testing kits” yields a panoply of DTC finger-stick tests: lipids (total, LDL, and HDL cholesterol; triglycerides), highsensitivity C-reactive protein (hs-CRP), aspartate aminotransferase/alanine aminotransferase (AST/ALT), hemoglobin A1c (Hb A1c), glucose, IgE allergy testing, Helicobacter pylori, hemoglobin, mononucleosis, prostate-specific antigen, and thyroid-stimulating hormone. Each test is performed in a nonclinical setting by a testing company, or the sample is collected at home with a kit and mailed in for analysis (e.g., Home Health Testing, Test Medical Symptoms At Home, Life Line Screening). These companies also perform testing in community settings, such as churches and schools, and results are provided at the point of care or after transport and laboratory processing.

These DTC finger-stick tests are often advertised for disease screening. One company, Life Line Screening, states, “This screening is a simple way for you to learn if your ALT/AST liver enzyme levels . . . suggest possible severe liver damage” (8). Even beyond disease “screening,” the company suggests this testing is especially useful for patients taking cholesterol-lowering statin therapy to monitor for statin-induced liver damage. Such suggestions indicate testing is being promoted beyond screening to diagnose adverse side effects of medications, actions that are arguably within the scope of medical practice. Indeed, some tests are specifically advertised for diagnosis. For example, TestCountry offers finger-stick H. pylori screening that is “designed to diagnose gastrointestinal symptoms in patients” (9).
Thus, although DTC medical-testing companies might purport to provide consumers with information regarding their own health, these companies are potentially engaged in the unauthorized practice of medicine. Furthermore, the limited oversight of this testing, combined with the lack of accountability for providing unauthorized medical care, allows these companies to avoid informed-consent discussions. Yet, such discussions are critical for patient safety and patients’ understanding of the risks and benefits of finger-stick testing.

Finger-Stick Testing Inaccuracies

The most commonly used finger-stick test is finger-stick glucose monitoring. Other tests, including international normalized ratio (INR), Hb A1c, and ketone testing, are being studied and clinically implemented on a much smaller scale. Even for the commonly used glucose finger-stick test, however, the literature abounds with studies highlighting dangers, inaccuracies, and limitations of the available finger-stick glucose-testing technology. And, although not every finger-stick glucose-testing system is subject to every one of these factors, potential dangers may arise from “strip factors” (e.g., test strip variation, testing-well depth/size variation), “physical factors” (e.g., altitude, temperature), and “patient factors” (e.g., coding errors, comorbid conditions, hand preparation, size of the capillary blood sample collected), all of which can affect testing accuracy and results (10).

Importantly, tests conducted with capillary blood obtained from finger-sticks may not be sufficiently analytically sensitive for routine screening purposes and may not produce an accuracy equivalent to that of standard testing with venous samples. Parikh and colleagues compared measurements of lipid and hs-CRP results obtained with finger-stick samples with those obtained with venous blood samples and found that the diagnostic sensitivity of finger-stick testing results for identifying abnormal lipid concentrations was <80% for all lipid categories (11). Worse, the diagnostic sensitivity of finger-stick testing for identifying abnormal hs-CRP concentrations was <75% (12). Another study evaluated finger-stick hemoglobin measurements and found diagnostic sensitivities between 25% and 72% for identifying women with low hemoglobin concentrations (13). Diagnostic sensitivity was even lower for men (12). These results indicate a likelihood of false-negative results and concomitant missed or delayed diagnoses when finger-stick testing is used for disease screening.

Another risk of finger-stick testing is lack of standardization. One study reported variation of 5.7%–32% in glucose measurements for >50% of side-by-side comparisons of 5 over-the-counter blood glucose monitors (13). Another study demonstrated that 6 of 8 commercially available finger-stick devices for Hb A1c testing do not meet widely accepted Hb A1c testing standards (14). These results suggest substantial concerns regarding test accuracy with DTC finger-stick testing in nonclinical settings, as well as at the point of care.

Furthermore, finger-stick testing devices are not self-explanatory and require a certain degree of proficiency to ensure accuracy. One study that evaluated the use of at-home INR testing provided 3643 patients with extensive training sessions to achieve competency with the finger-stick INR technology (15). Even with this training, 20% of patients (712 of 3643) still could not pass the competency test and were excluded (15). Consequently, even with legitimate, extensive, and standardized training, many patients may not be capable of performing finger-stick testing properly. Importantly, this limitation may apply to patients and DTC company technicians collecting the samples. DTC companies currently do not engage consumers in finger-stick training sessions prior to at-home self-testing, whereas finger-stick testing training is often offered to patients by a physician’s medical staff when the testing is ordered by a physician.

Finally, sample handling after DTC finger-stick testing carries the potential to introduce additional error. When test samples are subjected to mail or carrier transport for laboratory analysis, there is a potential for wear and tear, temperature variations, and altitude variations, all of which have been reported in the literature as capable of reducing result accuracy (10).

There are limited situations in which the benefits of using suboptimal testing outweigh the risks. These situations include diabetic glucose monitoring, urgent- and emergent-care situations in which waiting for the results of testing of venous samples can delay lifesaving care, or resource-limited settings where venous sampling is not viable. Outside these settings, however, there are major flaws of finger-stick testing when it is advertised and used DTC. These flaws should be highlighted and clearly communicated to consumers in the interest of providing patient/consumer safety and informed consent.

Regulatory Measures

There are many limitations of finger-stick testing for disease screening and diagnosis. Although healthcare professionals can help patients contextualize these limitations in informed-consent discussions, such guidance is absent in the DTC setting. None of the websites we assessed outlined risks, inaccuracies, and/or evidence-based use of any of the marketed testing. Furthermore, a major risk emerges when consumers re-
ceive DTC results and are led to believe they are definitively indicative regarding the presence or absence of disease. Patients are at high risk of forgoing needed care with a false-normal result. Conversely, patients with abnormal results are at risk of self-treating with pharmaceuticals purchased online without a prescription.

Hence, DTC medical testing should be viewed as medical practice. The diagnosis of disease has traditionally fallen within the domain of medical practice, so when companies offer or suggest diagnostic conclusions related to testing results, they are engaged in the practice of medicine. Therefore, state medical boards, medical councils, and other professional regulatory bodies should bring actions against these companies for unauthorized medical practice.

In parallel, the Food and Drug Administration (FDA), the regulatory body overseeing medical testing in the US, should focus on DTC companies as specific categories of clinical laboratories and therefore should regulate online claims and advertisements. At a minimum, offered tests should fulfill recent recommendations for DTC genetic testing, including FDA clearance, outcomes research prior to public availability, and testing through healthcare professionals. Ideally, oversight would include regulations requiring that the DTC company (a) provide evidence of effectiveness of the test for the suggested indication, (b) undergo monitored training and competence assessment of testing personnel, (c) undergo quality-assurance assessment for the testing modalities offered, (d) provide a balanced statement of risks and benefits in all advertisements, and (e) engage in an informed-consent process with patients/consumers. The rationale for regulating DTC finger-stick tests is similar to that of DTC genetic testing: patients are entitled to “assurances that test measurements are correct and that clinical claims are valid” (16).

Finally, we believe traditional informed-consent discussions should be obtained from consumers considering DTC testing. That would require standard descriptions of risks and benefits, hence ensuring that any claims could then be subject to accountability for lack of informed consent. In coordination, both DTC marketing accountability and patient safety and empowerment can ensure that consumers receive correct information and legitimate, evidence-based testing.

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