

Is Theranos procedure a healthcare industry revolution or a marketing phenomenon?

11 June 2015

Professor of Clinical Biochemistry Eleftherios P. Diamandis's recently published article in *Clinical Chemistry and Laboratory Medicine* shines a critical light on the company's claims.

The press is hailing it as a revolution in the healthcare industry: The fingerprick [test](#) procedure developed by Theranos can assess up to 200 different values from a single drop of blood and show indicators of potential medical conditions. With the company valued at nine billion dollars, its founder Elizabeth Holmes is America's youngest billionaire. It all seems like a fairytale success story.

In his article "Theranos Phenomenon: Promises and Fallacies," the distinguished Professor of Clinical Biochemistry Eleftherios P. Diamandis scrutinizes this perceived success. Through scrupulous examination of five key issues, he reaches the conclusion that many of the company's claims do not stand up to scientific review.

Diamandis's first concern is that Theranos's laboratory system was at no point subject to scientific assessment by an independent organization, as is customary in clinical research. In addition, laboratory results and other data were not made available for peer review and comparison by conventional test methods. Theranos keeps its laboratory system and data in strict secrecy. Transparency through publishing is absolutely indispensable in serious scientific practice, as it allows the quality of results to be assessed and verified.

Theranos claims that with its procedure, test results are available in less time and at lower cost compared to conventional laboratory testing. Diamandis questions the value of such generalized claims, which cannot be verified, in contrast to specific claims about specific tests. He points out that most laboratories deliver [test results](#) within

one or two hours; that, for a whole range of tests, speed is not necessarily beneficial for patients; and that larger laboratories can offer their services significantly cheaper than Theranos. The company's response to the latter issue, which is to claim that such laboratories require a separate blood sample for each individual test, is dismissed by Diamandis, as with a routine blood sample, a single tube of blood is sufficient to carry out between 10 and 100 conventional tests. Moreover, many, if not all, of Theranos' technological advances are now incorporated into widely used point-of-care devices.

Diamandis also considers how patients can be unsettled by over-diagnosis, may be overburdened by self-testing, and that over-treatment can have negative consequences. He also questions whether a fingerprick is really less painful than current methods of drawing blood, again arriving at conclusions at odds with Theranos's publicity.

Diamandis concludes by calling for open discussion of Theranos's procedure and results in the appropriate scientific journals and forums to allow better understanding of the benefits, but also the risks associated with the Theranos test procedure.

More information: "Theranos phenomenon: promises and fallacies." *Clinical Chemistry and Laboratory Medicine (CCLM)*. Volume 53, Issue 7, Pages 989–993, ISSN (Online) 1437-4331, ISSN (Print) 1434-6621, DOI: 10.1515/cclm-2015-0356

Provided by De Gruyter

APA citation: Is Theranos procedure a healthcare industry revolution or a marketing phenomenon? (2015, June 11) retrieved 25 September 2021 from <https://medicalxpress.com/news/2015-06-theranos-procedure-healthcare-industry-revolution.html>

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