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EDITORIAL

Decoupling knowledge and expertise in personalized medicine: who will fill the gap?

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Walk into many Arizona Walgreens these days and you will find that the pharmacy associated with it has a blood-testing center. There you can sit down and peruse a slick, glossy menu that lists more than 100 different blood tests for specific molecules or metabolites including tests for everything from Hepatitis B to C-reactive protein to glucose to cocaine. You can check off which ones you are interested in having performed and hand your choices to the pharmacist at the counter. Your list is scanned into a computer along with information about your identity and email address while you sit in the waiting area. Within the next 10 to 30 minutes, depending on how busy they are, a phlebotomist will invite you into a room and draw your blood. Typically, later that evening, you will get an email inviting you to log into your account and see the results.

This scenario illustrates that responsibility for interpreting health information is shifting from providers to consumers. Although it represents only one approach to direct-to-consumer (DTC) testing, and while not all DTC tests raise the same issues or require the same degree of interpretation, the shift raises nontrivial questions about the general conditions associated with the shifting of responsibilities over the reading, and interpretation, of health data and the potential empowerment, and/or disenfranchisement, of these consumers.

The ability for an individual in the state of Arizona to circumvent their physician and order clinical tests directly from the laboratory is not, in itself, new. As with a number of other states, DTC laboratory testing has been permitted within Arizona for a number of years. As provided for under Arizona Revised Statute § 36-466, an expert advisory committee was vested with authority to create a list of so-called 'direct access tests'; these authorized tests were then available to an individual under the DTC approach. The list, maintained by the Department of Health Services, provided for a select number, and very narrow types of DTC tests including, for example, cholesterol and glycated hemoglobin (HbA1c) levels. In this sense Arizona House Bill 2645 simply builds upon, and expands, Arizona's preexisting DTC framework, rather than creating it from scratch.

Arizona House Bill 2645 entered into force on 3 July 2015, at which time the state became only the second state, after Virginia, to expressly allow for unfettered DTC testing. That is, an individual may directly obtain 'any' test, without a physician's authorization, provided it is obtained from a certified lab. Across the United States, a 'spaghetti junction' of legal rules governing DTC testing currently exists, regulating direct access to familiar and everyday types of tests such as cholesterol (see, for example, [1]).

As noted by Parloff [2], these legislative approaches range from providing for unfettered testing (VA and AZ), limited access testing (9 states), through to the outright prohibition on DTC testing (13 states including, for example, California and New York) [3]. The legislature in the remaining states – and the District of Columbia – has, however, been silent on the issue. As suggested by Parloff [2], in these states and the District of Columbia – which represent the majority of states – silence on the part of the legislature may be interpreted as implicit consent for DTC testing. Whether this is true or not remains to be tested.

While idiosyncratic in nature, the legislative frameworks adopted in Virginia and Arizona share a number of key provisions. These include shielding healthcare providers from potential liability in cases where they did not review and/or act upon laboratory test results that they themselves did not order and/or authorize (see Ariz. Rev. Stat. § 36-466.C and Va. Code Ann. § 8.01-581.18 (2006)). Accordingly, the responsibility to interpret and/or act upon results from a DTC test falls squarely on the individual. While physicians are likely to applaud the inclusion of such immunity provisions in the legislation, it does raise questions regarding the capacity of individuals to effectively read their results and act in a timely and appropriate manner in order to protect, and promote, their health and wellbeing.

House Bill 2645 prohibits an Arizona laboratory from filing a reimbursement claim directly with an insurance provider, and does not require DTC testing to be covered by a third-party health-insurance plans (see Ariz. Rev. Stat. § 36-466.D and E). This does not mean, however, that an insurance company will not cover costs associated with a DTC test. Rather, that the burden to pay for the DTC test/s will fall on the individual at the time of the testing, and that reimbursement shall only occur after the fact (if at all). While this may present a barrier

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for some, the entry of players into the market, including, for example, Palo Alto-based Theranos, challenges this. Accordingly to their website, approximately 140 of the available tests listed on the test menu are less than $10 per test, and their 'prices are 50–80% off of Medicare reimbursement rates–and far below commercial lab prices' [4]. An AZ resident, or indeed any individual, may, for example, walk into one of Theranos's 42 so-called 'Wellness Centers' in Arizona and have their HbA1c tested for $6.61 or blood cholesterol for $2.96 [5]. This, we would argue, provides many consumers with – should they wish to exercise it – an unparalleled level of access to, and control over, their health information. What they then do with this information is another issue.

For instance, consider someone with a deep knowledge of biochemistry develops an interest in a recently developed product from the company Elysium Health [6] that claims to maintain a higher quality of life as one ages. In reading the primary literature, she finds that this product came out of research done at MIT, and she is intrigued by their initial results suggesting that the supplement appears to help optimize mitochondrial function in cells. She decides to experiment with it on herself, but, wary of possible side effects, first goes to her local Walgreens once a week for 3 weeks to get a baseline measure of her kidney and liver function using their 'Comprehensive Metabolic Panel' ($7.37). It turns out that one of her metabolite values was slightly high in one of the three panels, but she realizes that this is of no significance given that the high value only occurred once in one of the tests. She then starts taking the supplement, and continues to monitor organ function using this panel of tests, ensuring that the supplement (which is not subject to the strict regulation of therapeutic compounds by the FDA) is not adversely affecting her kidney or liver function.

By contrast, someone with less background in the area might become involved in a very different scenario. Consider an individual who received an advertisement from Elysium Health decides to take the supplement as directed. Sometime later, however, he reads on a blog that certain supplements can cause serious damage to multiple organs. After poking around on the Internet, he finds a list of tests that doctors perform to evaluate organ function, and he decides to have a metabolic panel performed at Walgreens. When the tests come back, one of the numbers is 10% high and flagged as above range, he takes this as confirmation of his concerns, not knowing (as the more experienced user did) that this result really means nothing on its own.

There are numerous reasons to applaud the decoupling of knowledge from expertise, both in general and in the case of promoting public health. Inexpensive and accessible DTC testing appears to be one approach to doing so. Potential benefits of services offered by, for example, the Wellness Centers may include, the following:

- greater access for consumers to their own medical information, including clinical results, directly and inexpensively;
- empowerment of citizens to take greater responsibility for their preventative health and wellness through access to good quality tests; and/or
- better quality health information through creation of new markets and healthy competition.

At the same time, a variety of social policy concerns have been raised in response to the prospect of such unfettered access to health information, including the following:

- potential for over-testing (i.e., people get 'addicted' to knowing their numbers, and become serial consumers of the DTC services);
- safety risks from unreliable and/or complicated tests, particularly in the case of genetic testing [7] which may have the capacity to undermine public health efforts; and/or
- potential to undermine the physician–patient relationship, and what this may do in relation to quality of care.

Such lists of theoretical benefits and risks are increasingly easy to find in the commentaries on personalized medicine, and the trend will no doubt continue as advances in medical science, novel business models, and conflicting policy mandates proliferate. In due time, as DTC becomes more widespread and utilized, data to either support and/or challenge such lists will be collected and published. Then we will be able to better assess the true value and/or risks of DTC testing, including its impact on public health more generally.

Underlying the uncertainties surrounding the decoupling of information from expertise, however, is a more fundamental question: as responsibility for interpreting health information shifts from providers to consumers, what factors will make the difference between empowerment versus disenfranchisement?

The answer to this question will depend, in large part, on the quality and availability of information and advice that consumers employ to fill the gap between information and expertise. Traditional forms of medical expertise will no doubt remain on top, if not on top as the saying goes, for the foreseeable future. But for biohackers [8], citizen scientists [9], and other experimentalists who chose instead to bypass such expertise and mobilize their own knowledge and experience, one can already detect emerging networks [10] and markets [11] for disruptive or do-it-yourself health care. If, as we argue, new forms of information and advice continue to emerge, not only for genetic tests but also for more routine tests, policy makers should be prepared to anticipate complex future developments. As the cost of testing goes down, for instance, demand for counseling services could rise. Consumers deserve more than a simple binary choice between expensive healthcare boutiques versus an abundance of easily searchable popular heuristics. As an alternative, either through bottom-up efforts or through state-led provision of public goods, new public health boundary organizations [12] that could take the form of sponsored networks, community clinics, or information clearing houses, could act as honest brokers [13], vetting and facilitating the exchange of information to inform and facilitate social learning.

The passage of the Patient Protection and Affordable Care Act (Public Law 111-148), with its focus on population health and preventative care, ushered in a new era of health care in the United States. DTC testing, albeit under an unfettered or

limited access framework, appears to be a tool that individuals may use in order to help promote well-being. Whether or not legislation such as Ariz. House Bill 2645 results in increased level of laboratory testing remains to be seen. Moreover, whether or not such services result in better health outcomes at the individual or population level, is a question that is unlikely to be answered for a number of years (if indeed, it can be). Still, studies monitoring how individuals' interpretations of data influence their healthcare use and behavior have begun to appear [14]. As the legal patchwork suggests, views on DTC vary widely, so efforts to understand and strengthen the connection between DTC and wellness could play a crucial role in brokering a more informed public debate.

In conclusion, early anticipation of uncertain outcomes along with real-time monitoring of the situation and experimental provisions to facilitate social learning could help ensure that more health information indeed translates into more wellness.

Declaration of interest

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