

## EDITORIALS

# The Case Against Marketing Genetic Tests to Primary Care Doctors to Promote Test Ordering

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Over the past decade there has been an enormous increase in the availability of and demand for genetic tests. The appropriate use of genetic tests has the potential to enhance both the quality and length of human life. Not surprisingly, numerous stakeholder groups have emerged seeking to influence the medical profession and the public in an attempt to guide genetic test use. Some of these groups offer advice based on their expertise and scientific evidence; others are driven by profit.

When ordering genetic tests, we need to remember that the screening tests are similar to other screening tests we often order, same basic principles should apply as to other screening tests (PSA, colonoscopy, etc.). Clear criteria are already established for appropriate use of screening tests.<sup>1</sup> Readers of *JGIM* need only a reminder that genetic testing is most useful when 1) a person has a personal or family history that increases their risk for a genetic syndrome; 2) the results of the test can be interpreted, and 3) the testing will influence medical management.

Certainly issues unique to genetic testing include ethical dilemmas involving families, discrimination, and stigma. The public often is confused by genetics, and some people hold beliefs that are not consistent with accepted medical understanding. As a result, our patients may make clinical choices based on erroneous assumptions. All of this suggests a vital role for patient education and makes the case for careful shared decision-making between physicians and patients.

Haga<sup>2</sup> and colleagues present a cross sectional study of 356 primary care physicians with a 44% response rate. The study examines several issues related to genetic profiling (a statistical process of looking for “risk patterns” of complex diseases such as obesity and diabetes). It is important to understand that genetic profiling is *not* susceptibility testing (e.g., BRCA testing) which is intended to look for specific gene mutations associated with specific diseases. Instead, genetic profiling looks at single nucleotide polymorphisms (SNPs) in an attempt to identify potential risk information only by statistical association. In theory, the benefit of genetic profiling (as opposed to susceptibility testing) is to encourage disease prevention by encouraging healthy behavior change. However, to date there have been no proven direct benefits from genetic profiling.

Haga’s research design was to survey a national practice group of primary care physicians (MDVIP) that started offering genomic risk profiling as a part of their routine practice. This national practice group had recently announced a “collabora-

tion” with the for-profit company Navigenics which heavily markets genetic tests to physicians and the public. Part of this “collaboration” involved an offer by Navigenics to provide as a gift, a personalized genetic profile to all MDVIP physicians.<sup>2</sup> Is it possible that this offer of free genetic testing to doctors had as the primary goal of helping to promote the test and increase company profits?

One important finding from Haga’s study was that one third of physicians offered a free genetic profile (cost=\$999) accepted the offer. Not surprisingly, those who accepted the free offer were eight times more likely to order the genetic test on their patients compared to those who did not accept the free offer. The low response rate in Haga’s study precludes us from making any broad assumptions of physician behavior; although, hidden in her study are two important social issues that deserve comment.

Our patients trust us, and need to trust us, to provide them advice based on what we believe is in their best interest and not influenced by other considerations such as gifts or perks that the doctor receives. Did the MDVIP leadership not consider a \$999 offer of a free laboratory test a gift intended to influence the doctor’s practice behaviors? Did they naively believe that Navigenics was offering this free testing based on an altruistic concern over the health of MDVIP doctors? Could it be that Navigenics knew that an offer of free tests to doctors would increase test ordering for patients? Could it be that this was the basis of their promotional campaign—getting doctors to agree to genetic testing by offering it to them for free?”

An offer of an incentive (in this case a free genetic test) from a new “collaborator” should clearly have raised questions for every one of the doctors. Even if any given doctor genuinely believed the test was in the best interest of a patient, it would be difficult to argue that the test ordering wasn’t influenced by a favor provided by Navigenics with an implicit expectation of reciprocity (“we did you a favor, now it is expected you will do us a favor by ordering this test on your patients”).<sup>3</sup> Is this type of social influence any different than offer of free drugs to doctors by pharmaceutical companies in an attempt to build loyalty?

When there is, or when there should be, concern over whether a conflict of interest exists, doctors should be open with patients and describe the nature of the gift they received, be it tickets to a dinner or sporting event, a free expensive genetics test, or even a free CME course funded and delivered by the makers of a genetic test (as was also done in this “collaboration”). I wonder if any MDVIP physicians ever told their patients that they received a free gift by the very company that profited from the test the doctor was about to order—a test that has no proven value to the patient? Similarly, prior to testing, did the physicians include in their conversations with patients a discussion around informed consent?<sup>4</sup>

It matters not if the physician *believed* that the gift (or all the promotional materials left in patient waiting areas) did not influence their practice behaviors (as most physicians do despite mountains of evidence to the contrary). Nor does it matter that the doctor might perceive the \$999 gift to be relatively small and insignificant relative to their overall salary. Full disclosure is required to avoid undermining patient trust.

The second major issue raised in this paper has to do with physician education. Haga clearly and accurately points out that physicians' knowledge around genetic testing is very limited perhaps because the vast majority of practicing physicians graduated from medical school well before the common use of clinical genetic tests. Yet, rather than providing physicians with evidenced-based education using modern educational methods (which are available from many reputable professional groups that have no commercial bias) MDVIP opted instead to provide its doctors with genetics "educational material" developed by Navigenics. Might there be a potential for lack of balance in this educational material? Might such a campaign be more accurately categorized as promotional rather than educational?

It seems we have been round this issue before with pharmaceuticals and medical devices. As a profession, haven't we decided that education developed by a company with a vested interest in the physician's practice outcomes is not ethically or educationally appropriate?

As we move toward some sort of health reform, there will be an important need to limit unnecessary spending starting with expensive testing that is not evidenced based. We have already seen that those who stand to lose profit from reform

see no limits to working behind the scene to lobby policy makers, professional groups, and, in this case, individual physicians.

Primary care doctors can either be part of the problem or we can be part of the solution by being vigilant and by self policing to avoid any actual or perceived conflicts of interest in order to maintain the trust of our patients and society. We also need to be informed consumers when it comes to our own education and avoid all commercial influence that seeks to promote profit at the expense of patient well being.

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