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Challenges in the Use of Direct-to-Consumer Personal Genome Testing in Children

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In the target article, McGuire and colleagues (2009) found that 54% of social networkers would consider using direct-to-consumer personal genome testing (DTC PGT) for their child and that 63% agreed that parents should be able to have their children tested with DTC PGT (McGuire et al. 2009). These results suggest that the use of DTC PGT may significantly broaden the scope of pediatric genetic testing. Currently, some DTC PGT companies seem to simultaneously promote and discourage use of their services for children. For example, 23andMe suggests on its website that, its services are not "designed or intended to attract children under the age of 13" (23andMe 2009a), yet suggests that consumers can, "Add some excitement to your family reunion by comparing the DNA of children with other relatives" (23andMe 2009b). What are the ethical considerations of DTC PGT in children and how should they be addressed?

Genetic testing in children is not a new challenge. Guidelines by the American Society of Human Genetics/American College of Medical Genetics (1995) and by the American Academy of Pediatrics (2001) address the use of genetic tests in children. These guidelines are based on a medical model of genetic testing that presumes the involvement of a clinician who has certain obligations to parents and children. The clinician acts as a gatekeeper, informing decisions about risk and benefit and determining whether testing is appropriate. The guidelines acknowledge that the risk-benefit ratio of much genetic information is unclear, and that in the absence of information, providers "may be obligated to avoid the possibility of harm, rather than to provide unclear benefits" (American Society of Human Genetics 1995, 1238).

In contrast, the direct-to-consumer model, by definition, bypasses the medical gatekeeper and their guidance. As consumers of DTC PGT services, parents may not prioritize consideration of medical benefit to their children in the same way as parents of patients. Users of DTC PGT may include families who are not likely or able to obtain genetic testing under the traditional medical model, including families not at risk for any rare genetic diseases. For these reasons, in a DTC PGT model, considerations of medical benefit may be either absent or minimal.

Outside a medical model of benefit, the key question becomes: what harms are associated with DTC PGT in children and do they differ from harms associated with medical genetic testing

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in children? Wilfond and Ross (2008) have suggested that genetic testing in children should be guided by parental-decision making "unless empirical social and behavioral data indicate that genetic testing is highly likely to cause serious harms to children" (1). Unfortunately, there are no empirical data on the harms of DTC PGT in children, including whether they differ from harms in a medical delivery model or whether they differ across populations and reasons for obtaining the service.

Because DTC PGT shifts genetic testing from a physician-parent relationship to an institution-consumer relationship, it may be unclear who is responsible for minimizing harms. While the DTC PGT companies act as providers of the service, they do not assume the same kinds of obligations as a medical provider. Assent of the child is not required, and there appears to be no provision of information about the possible risks of genetic information to children or consideration of risk-benefit ratios. Furthermore, the scope of obligation to provide benefit is as yet unclear. We will illustrate some of the concerns raised by DTC PGT in children through two scenarios, using the services offered by 23andme as an example. These scenarios demonstrate the challenges in applying current guidelines on genetic testing in children and suggest the need to develop guidelines specific to the DTC PGT arena.

Carrier Testing

One of the main features of DTC PGT is the ability to test for carrier status for a range of rare genetic disorders. The consumers of this information may include parents who have specific reasons to suspect that their children may be at risk for these traits, but will also include parents who participate in DTC PGT for 'recreational purposes'. These parents likely will not anticipate receiving this information or consider what it might mean for their child or family.

Existing guidelines recommend against carrier screening in children, arguing that there is no medical benefit of carrier information to the child and that the future reproductive benefit may be very limited. The guidelines also argue that there is historical and empirical evidence of a high likelihood of "individual and community misunderstanding of the carrier state," recalling the history of misunderstandings and discrimination around sickle cell carrier testing. (American Academy of Pediatrics 2001; Wailoo and Pemberton 2006) The guidelines also suggest that, "children and adolescents may be more psychologically vulnerable than adults to knowledge of carrier state" (American Academy of Pediatrics 2001, 1453) suggesting that they merit additional protections from this information, especially when it does not provide benefit.

How should DTC PGT companies address carrier testing in children? At a minimum, parents need guidance from companies about the risks and benefits of carrier testing in children. Requiring parents to participate in online education about the absence of benefit and potential psychosocial harms would help address these concerns. If parents choose DTC PGT testing for their children, they could be encouraged to opt out of receiving carrier test data for rare genetic traits, particularly if they have no reason to be concerned about increased family risk. Providing genetic counselors to help interpret carrier testing would also minimize misinterpretation of results. While these efforts would not avoid all possible harms or misinterpretation, they would significantly limit them.

Social Networking

As the target article illustrates, some parents may also use DTC PGT for social networking. Social networking and data sharing among family and friends are key features of 23andme marketing, described as part of the "fun" of genetics around traits such as eye color or food preference (23andMe 2009b). Given the increase in DTC PGT disease tests, it is likely that social networking might include sharing of more clinically meaningful, and possibly more stigmatizing information. Just as genetics may increase psychological bonding with relatives

over shared traits, it may also increase distress around sharing of disease risks for debilitating diseases that older relatives are suffering, such as breast cancer, Parkinson's disease, or macular degeneration. There are no data about how children might react to this kind of information or how it might influence their interactions with family members.

Social networking may also take place around unusual genetic results related to specific diseases. In December 2007, the *New York Times* described how families with rare genetic conditions diagnosed through traditional genetic testing use social networking and the Internet to connect with others going through similar experiences to provide support, advice and "kinship" (Harmon 2008, A1). DTC PGT services may facilitate this form of social networking, providing direct benefit to families and children.

Although there may be benefits, the privacy and autonomy of children is challenged by DTC PGT social networking. When parents share genetic data about their children through internet-mediated social networks, children's privacy is vulnerable because the DTC PGT context may lack the privacy protections and obligations of a health care setting, including protections of the Health Insurance Portability and Accountability Act (HIPAA). Perhaps most concerning to children is the potential future infringements of their privacy. Once their genetic data has been shared through social networking it is likely impossible to retract. Recent data suggests that even "de-identified" genetic data may be identifiable using statistical methods and limited phenotypic data, meaning that their genetic information may be unintentionally shared with a much wider network of people in their future without their consent (Resnik 2009).

One way to address these concerns would be for DTC PGT companies to discourage parents from sharing children's data and instead delay until their children can consent for themselves. Social networking could still be facilitated among parents of children with specific diseases, as this is similar to social networking in disease support and advocacy groups. However, this networking could take place without the sharing of other genetic information, specifically without allowing others to view the entire DTC PGT data of children. The American Society of Human Genetics Statement on DTC testing recommends that DTC PGT companies "maintain the privacy of all genetic information and disclose their privacy policies, including whether they comply with HIPAA." We agree and believe transparency about privacy policies is also important for the protection of children's future privacy rights (Hudson et al. 2007).

We have highlighted just a few of the serious concerns surrounding the use of DTC PGT in children. Because DTC PGT is a new service, more research is needed. Specifically, who will use the services and how will children respond to and process different kinds of PGT data? What are the immediate and long-term impacts of DTC PGT in children? Empirical data on these questions is needed to inform guidelines specific to DTC PGT in children. Until more is understood about this kind of testing, DTC PGT companies should act with caution to protect the best interests and autonomy of children and to minimize any potential harms resulting from the use of their services in children.

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