

ARTICLE

Are the kids really all right?

Direct-to-consumer genetic testing in children: are company policies clashing with professional norms?

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The genetic testing of minors within the direct-to-consumer (DTC) genetic testing (GT) context has been given relatively little attention. The issue of testing healthy children for diseases that would only develop in adulthood raises many important ethical, legal and social issues. As genetic testing is now available outside of the traditional health care system, often without even the intermediate of a health care professional, we surveyed 37 DTC GT companies regarding their policies for testing in children. Although the response rate is relatively low (35%, 13/37), our findings reveal that a clear majority of companies do perform genetic testing in minors. As such, companies testing for adult onset diseases are acting in contradiction of established professional guidelines, which state, among others, that, for predictive genetic testing, the availability of therapeutic or preventive measures is necessary for testing to be performed in asymptomatic minors. The community of stakeholders in children's health care and genetic testing should, therefore, decide which standards need to be upheld by DTC GT companies and ensure that these are met.

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INTRODUCTION

Direct-to-consumer (DTC) genetic testing (GT) involves either the marketing and/or the offer of genetic tests directly to the public, often without any involvement from health care professionals. It is not, strictly speaking, a new phenomenon; the Advisory Committee on Genetic Testing (ACGT, UK) made provisions for these types of services over a decade ago.¹ Sciona, a company selling nutrigenomic testing DTC in the UK was in operation by the year 2000,² and authors like Williams-Jones,³ Caulfield *et al*⁴ and Hotlzman⁵ were addressing the issue in academic journals well before Time Magazine declared the retail DNA test as the invention of the year in 2008. (http://www.time.com/time/specials/packages/article/0,28804,1852747_1854493,00.html). The renewed and intensified interest in these commercial activities, however, began in 2006–2007, and were partly sparked by the offer of genome-wide-testing (GWT) services from companies like deCODE (Reykjavik, Iceland) and 23andMe (Mountain View, CA, USA). The ensuing rapid increase in the number of companies selling all types of DTC GT (not only GWT) and the resulting eruption of scientific, ethical, legal and social debates have kept this phenomenon in the headlines of both the popular press^{6–9} and academic journals.^{10–12}

The scientific debate has centred mainly on the clinical validity and utility of offering risk estimates for complex disorders, for which, the detailed evidence for the involvement of specific genetic variants is still debatable.¹³ Meanwhile, the regulatory issues have taken centre stage since the spring and summer of 2010, when the FDA showed signs of

increasing the regulatory control of DTC GT companies' activities.^{14,15} Ethical and social concerns include, among others, the concerns regarding the absence and/or quality of the pre- and post-test genetic counselling,¹⁶ as well as with the absence of individualised medical supervision.¹⁷ Additional worries stem from the research activities of DTC GT companies,¹⁸ the (lack of) respect for privacy and the potential burden on the public health care system.¹⁹ A further concern, and one that has been relatively neglected in debates, is the subject of inappropriate genetic testing of minors.^{20,21}

The controversies regarding the predictive genetic testing of asymptomatic minors have been raised in previous policy statements from various professional organisations.^{22–25} The offer of such testing directly to the public has served to amplify existing concerns, as well as add new issues. With respect to the presymptomatic and predictive genetic testing of children, in general, guidelines recommend that the availability of therapeutic or preventive measures are necessary for testing to be performed in asymptomatic minors.^{26,27} In order to protect the privacy and confidentiality of genetic information and the minor's right not to know, it is suggested that testing asymptomatic children when there is no urgent medical need, be postponed until a minor can participate in the decision-making process.^{26,27}

We have previously studied the issue of DTC GT for health-related traits in children by conducting a content analysis of DTC GT companies' websites.^{20,21} In our most recent study, results showed

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that of the 29 companies studied; almost a third of companies perform genetic testing in minors upon parental request.²¹ Of the remaining companies, four explicitly state that their tests are not directed toward minors, and 17 companies either do not mention anything about testing minors or are not explicit about how they would deal with a request to test a child. Given the problems with conducting website-based content analysis,²⁸ as well as with the missing data from many companies, we followed up this content analysis with a questionnaire aimed at obtaining information regarding the policies on genetic testing in children directly from the companies selling these tests.

MATERIALS AND METHODS

Survey design and administration

A survey was developed with a total of 12 questions, eight closed-ended (mostly yes–or no) questions and four open-ended questions that allowed respondents to elaborate on their closed-ended answers. The questions addressed the testing policies of DTC GT companies with respect to genetic testing in minors (Table 1). The survey length was purposefully kept short to encourage a higher response rate. In the letter inviting companies to take part in our study, we assured them that anonymity of results would be secured and that the names of companies would not be divulged. The online software tool called Survey-Gizmo (<http://www.surveygizmo.com/>) was used to administer the survey. Companies were sent a ‘mass’ impersonal email (via SurveyGizmo), inviting them to answer the survey online. E-mails were sent to email addresses obtained from company websites under ‘contact’ information or were obtained after requesting a contact email via a companies’ online mail form. Four additional emails were sent as reminders to complete the questionnaire at 2–3 week intervals between December 2009 and April 2010. Finally, companies who had still not responded after four invitations were sent individual personal emails via the specific email addresses of the contact persons or known associates of the companies.

Companies

An Internet search for companies offering and/or marketing genetic testing services DTC was performed in July 2009. Combinations of the key words ‘direct-to-consumer’, ‘company’, ‘genetic testing’, and ‘genome’ were used with the search engine Google, as well as in the database Pubmed. For the latter, companies were identified via academic articles discussing DTC GT. All companies that described genetic or genomic testing services that could be ordered directly by consumers (through an online form, fax, telephone or e-mail request) for the purpose of testing human DNA were included. Companies were excluded if their webpage content was in a language other than English and if they offered: (i) educational information, without providing a DNA testing service that consumers were able to purchase; (ii) a service that was only for physician or clinical laboratory use; (iii) genetic analysis for plants, livestock or household pets exclusively; or (iv) genetic tests only for relationship compatibility.

RESULTS

Companies and response rate

Our search strategy resulted in a list of 48 companies, mostly based in the USA, selling genetic testing DTC. The types of tests sold included GWT, single gene tests and multi-gene tests. The range of tests included, but were not limited to, tests for paternity, monogenic diseases (ie, cystic fibrosis, Tay-Sachs) common complex diseases (ie, cardiovascular diseases, colon cancer, bipolar disorder), pharmacogenomics and nutrigenomics. From this set of 48 companies, email contact information was obtained for 37 companies. Of the remaining 11 companies, four websites were no longer functioning, two companies had email addresses that were no longer functional and five companies did not respond to our request for a contact email address. Therefore, 37 companies were contacted through email between December 2009 and April 2010, with a request to complete the online

survey. Of the 37 companies to which invitations were sent to complete the survey, 13 (35%) filled out and submitted the questionnaire. On the basis of ‘contact’ information provided on these companies’ websites, it would appear that the majority of companies are based in North America; eight companies are based in the USA, two are based in Canada, two are based in the UK and one has headquarters in both the USA and the UK.

Questionnaire answers

The responses to the closed-ended questions of the survey are included in Table 1. A large majority of companies (9/13, 69%) have received requests from parents or legal guardians to test minors and most of them (10/13, 77%) do perform genetic testing in minors under parental or legal guardian requests. From the elaborations made by companies about this question, we clearly see a large variation in company attitudes towards this subject. One company that does not test minors stated:

‘The type of testing that we offer does not have proven relevance to minors since the panel addresses risks for adult-onset diseases. Further, in order to offer testing to minors there would need to be a separate consent process for guardians/ assent process for adolescents that would require different protocols than are currently in place.’ Company Q.

Meanwhile, one company claims that the testing of children may be a by-product of their privacy policies:

‘Our business model provides complete consumer anonymity, thus we do not know who is being tested, what their age is or any other personal information.’ They also go on to say that ‘A purist would argue that we allow the testing of minors, without their consent and that this could somehow be to the minors detriment. It is difficult to conceive why anyone would bother to spend money testing a minor for the types of products that we offer in an effort to harm them. Our products are designed to provide the consumer with information about their genetic predispositions that allow them to take positive steps in the areas where they are at increased risk.’ Company O.

Yet, another stance from companies is that genetic testing in children can be positive.

‘Non-medical genetic information can help parents better understand their child’s innate strengths and weaknesses, and help in successfully raising the child.’ Company U.
‘Our genetic tests, which are both predictive and clinical in nature, can be useful tools in the diagnosis, prevention, and treatment of a wide range of health conditions. The benefits of this function are not limited to individuals over the age of 18, and therefore we believe that – with parental consent and the guidance and interpretation of a qualified physician – our tests may be performed on minors as well as on adults.’ Company S.

Furthermore, three of these companies would also consider performing testing if requested by a minor. One of these companies, however, states that they would only do this ‘if they are emancipated minors.’ That being said, only one company has received a direct request from a minor for genetic testing. Moreover, three of the 13 companies reported that they do perform research on samples/data originating from minors. The minority of companies (4/13) claim to require a consultation with a qualified medical doctor in order to purchase a genetic test; of these, three companies state that this happens face-to-face and one company says it happens by telephone or face-to-face. Interestingly, one company

Table 1 Survey questions and responses

Survey questions	Possible answers	Number of respondents
1. Has your company ever received requests from parents or legal guardians for the genetic testing of children younger than 18 years?	Yes	9
	No	4
2. Has your company ever received requests from children younger than 18 years of age for genetic testing without parental consent or authorization?	Yes	1
	No	12
3. Does your company perform genetic testing in children younger than 18 years of age upon parental request?	Yes	10
	No	3
4. Does your company allow children under the age of 18 to order genetic tests without parental consent or authorization?	In some cases	3
	Never	10
5. Is your company policy based on a specific professional guideline?	Yes	3
	No	10
6. Do you perform research on samples and/or data from children younger than 18 years of age?	Yes	3
	No	9
	No answer	1
7. Do you require that consumers have a consultation with a qualified medical doctor in order to purchase a genetic test?	Yes	4
	No	9
8. If there is a consultation with a qualified medical doctor, is the consultation by telephone, face-to-face or other?	Only face-to-face	3
	Face-to-face or telephone	1

that does not require such consultation before purchasing a test say that it is the consumer's responsibility to consult a health care professional:

'Each person ordering a test from our company must agree to the terms and conditions of the transaction, and these terms and conditions include an acknowledgement that the results of any tests performed will be interpreted in consultation with a qualified physician.' Company S.

Finally, most companies' policies regarding testing in minors are not based on professional guidelines. One of the few companies that reported that they do follow professional guidelines mentioned guidelines from the American College of Medical Genetics and the World Health Organisation. Another company that also state they are following guidelines referred to their 'own guidelines and follow US and European recommendations.' Company Y.

DISCUSSION

Only a minority of the DTC GT companies invited to participate chose to take part in our study, which resulted in a relatively low response rate. That being said, it must be noted that we invited almost the entirety of the population of DTC GT companies (with English websites) to participate in this study (as opposed to sampling a small section of a large population). Therefore, the information obtained from the relatively small pool of respondents can, nonetheless, be considered informative in this context.

Our focus was on companies that offer GT DTC. It was, therefore, surprising to find that four respondents answered the question regarding a prerequisite consultation with a health care professional by stating that they do require such a consultation before consumers can purchase a test. In light of these findings, we returned to verify these four companies' websites regarding how genetic tests were being offered. Although some company sites did mention health care professional involvement, none specified the prerequisite for a consultation with a qualified medical doctor in order to purchase a genetic test. This may mean that information on websites is not

completely representative of what companies are actually doing. It may also be indicative of the new trend in DTC GT, whereby some companies have now changed their business model and are requiring consumers to order testing via a medical doctor.

The fact that three companies perform research, using data/samples from minors, is a concern. First of all, research performed by DTC GT companies is already contentious, as the blurring between consumer and research subject can compromise the informed consent process.¹⁸ Above and beyond this, the fact that research is being performed on DNA samples originating from minors may also raise important issues. A review of guidelines on the topic by Hens *et al*²⁹ shows that there is no systematic agreement on all relevant themes. However, if we simply look at two of the important themes the review discusses, the need for ethics committee approval and the principles of non-therapeutic research on vulnerable populations, conflicts become likely. For one, as far as information on websites reveals, most companies do not undergo ethics committee approval. Second, the fact that many companies test for adult onset disorders (and may, therefore, perform research on these disorders using samples from minors) clashes with the principles that research should only be done in minors if (i) it benefits persons of the same age or condition, (ii) it can have direct benefit to the participant and (iii) the same research can not be carried out on adults.²⁹

Foremost, our data confirm that a large majority of companies selling GT DTC are testing minors. In attempting to keep the questionnaire short, questions regarding the nature of the tests being performed were not posed. We are, obviously, aware that performing a genetic test in a child for susceptibility to gluten insensitivity does not pose the same ethical, psychological and emotional concerns as does a test for Huntington or breast cancer. Although there is some debate over the matter, many professional guidelines recommend that for predictive GT, the availability of medical intervention or preventive measures is necessary for testing to be performed in asymptomatic minors.²⁷ Furthermore, in order to protect the privacy and confidentiality of genetic information and the

minor's right 'not to know', it is suggested that in the absence of medical urgency, the testing of asymptomatic children should be postponed until an individual can participate in the decision-making process and make an informed choice.²⁷ For example, in accordance with other recommendations, the British Society for Human Genetics (BSHG) recommends that 'testing should normally be delayed until the young person can decide for him/herself when, or whether to be tested'.³⁰ The BSHG also explicitly states that 'this does not mean that childhood testing for such conditions should never be done.' It is recommended that when a parent requests to have a child tested and that this test has no direct or immediate medical benefits, 'an assessment should be made of the balance of harms and benefits' taking into account the child's best interests.³⁰

With respect to guidelines specific to DTC GT, the European Society of Human Genetics in their statement on DTC health-related GT, states that '...The very context of DTC genetic testing does not allow for an adequate assessment of the competence of a minor. Therefore, the ESHG considers that DTC genetic tests should not be offered to individuals who have not reached the age of legal majority'.³¹ Meanwhile, the Human Genetics Commission³² document entitled 'Common framework of principles for DTC GT services' states in principle 6.9:

'The following principle applies to tests in categories 1-3**, 5** and 6** (and categories 7** and 8** where these have been evaluated as 'high impact' – see 'How to use the Principles'). Genetic tests in respect of children when, according to applicable law, that child does not have capacity to consent should normally be deferred until the attainment of such capacity, unless other factors indicate that testing during childhood is clinically indicated. If postponement would be detrimental to the child's health, or the management of the child's health may be altered significantly depending on the test result, then testing should be organised by a health professional who has responsibility for ensuring that any medical intervention or screening indicated will be arranged and proper arrangements made for any subsequent care.'

**where 1=diagnostic, 2=pre-symptomatic, 3=carrier, 5=susceptibility, 6=pharmacogenomic, 7=nutrigenomic, 8=lifestyle.

The Nuffield Council on Bioethics³³ report 'Medical profiling and online medicine: the ethics of 'personalised healthcare' in a consumer age' published in October 2010, states that 'Firms should not knowingly analyse the DNA of children unless the requirement of clinical validity is met.' It goes on to say that '(iv) companies should not knowingly carry out for children DNA tests that do not meet the criteria of the UK National Screening Committee'.³³

Finally, as the majority of companies (11/13) surveyed are (at least partly) based in North America, it is pertinent to question whether there are any regional/national factors that could be contributing to the companies' attitudes regarding GT in children. Although a complete answer to this question would have to encompass more issues (including economical, ethical, legal, cultural, etc) than can be addressed here, we can highlight a few points. First of all, if we look at the guidelines for genetic testing in children, the review by Borry *et al*²⁷ did not report any outstanding differences between geographic locations. Second, if we address the issue of DTC GT, it should be noted that this offer, without a qualified health care professional, is not permitted in some European countries (ie, the Netherlands).³⁴ That being said, it is also true that such DTC GT is not permitted in 13 American states (ie, Georgia, Idaho)³⁵ and the FDA has held meetings

in the last year, suggesting that there will be increased oversight of DTC GT.¹⁵ Therefore, if there are differences in attitudes between North American and non-North American-based companies, these (and their causes) may be difficult to identify (and support with concrete examples), yet merit to be studied further.

CONCLUSION

Given the wide number and types of conditions and traits for which DTC GT is presently offered, it is clear that many companies selling DTC GT and testing children are doing so in contradiction with both clinical and DTC GT-specific guidelines. Furthermore, it would appear that almost none of the companies who replied to our survey have based their GT policy for children on guidelines submitted by professional organisations or societies, government bodies or other recommendation-issuing organisations. Why is this so? Do companies simply assume they do not have to adhere to existing clinical guidelines? Are companies lacking a clear understanding of the consequences of testing minors? These questions were beyond the scope of this study, but need to be addressed to ensure the protection of a vulnerable population. This question of whether DTC GT companies must adhere to the same technical and ethical guidelines as academic researchers and clinicians (from the traditional health care system) has also been posed with respect to research activities,³⁶ as well as for thresholds of clinical validity and utility. One could argue, however, that for these last two issues, there are no clear and generally accepted guidelines. Moreover, as discussed earlier, this is not the case for GT in children. There are clear positions adopted by the majority of clinicians, and if these guidelines are to be meaningful, we cannot simply overlook them, because companies are selling genetic tests for profit. This would invalidate the entire logic and value-based-framework on which the guidelines were originally built. Therefore, the community of stakeholders in children's health care and GT must be clear about which standards need to be upheld by DTC GT companies and ensure that these are met.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

DTC, direct-to-consumer; GT, genetic testing; GWT, genome wide testing

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