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ORIGINAL RESEARCH

Online direct-to-consumer messages about non-invasive prenatal genetic testing

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Abstract Non-invasive prenatal testing (NIPT) has been integrated into clinical care at a time when patients and healthcare providers increasingly utilize the internet to access health information. This study evaluated online direct-to-consumer information about NIPT produced by commercial laboratories accessible to both patients and healthcare providers. A coding checklist captured areas to describe content and assess concordance with clinical guidelines. We found that the information presented about NIPT is highly variable, both within a single website and broadly across all websites. Variability was noted in how NIPT is characterized, including test characteristics and indications. All laboratories offer NIPT to test for common sex chromosome aneuploidies, although there is a lack of consistency regarding the conditions offered and information provided about each. Although indicated for a subset of women at increased risk of aneuploidy, some laboratories describe the use of NIPT for all pregnant women. A subset of laboratories offers screening for microdeletions, although clinical practice guidelines do not yet recommend for general use for this indication. None of the online materials addressed the ethical issues associated with NIPT. This study highlights the need for clear, consistent, and evidence-based materials to educate patients and healthcare providers about the current and emerging applications of NIPT.

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Introduction

Non-invasive prenatal testing (NIPT) uses cell-free fetal DNA (cff DNA) to assess the risk of fetal trisomy 21, trisomy 18 and trisomy 13, with a greater sensitivity and specificity than conventional serum analyte screening tests (Bianchi et al., 2014; Norton et al., 2012). In addition, NIPT can be used to identify sex chromosome aneuploidies (SCA) that formerly could be detected only by using invasive diagnostic procedures. Currently, as outlined by clinical practice guidelines, NIPT is indicated for these conditions and for pregnant women who, on the basis of maternal age, reproductive history or a positive finding on other screening tests, are at increased risk for fetal aneuploidies (ACOG, 2015; Benn et al., 2013; Devers et al., 2013; Dondorp et al., 2015; Gregg et al., 2013). However, the use of NIPT in the general obstetric population is forthcoming (Greene et al., 2013; Wapner et al., 2015).

NIPT can be differentiated from conventional screens in two main ways. First, it can screen for a larger number of chromosomal aneuploidies than serum analyte screens can. Furthermore, because of the rapid pace of cff DNA technology, the capability of NIPT has quickly expanded to include the ability to identify subchromosomal variants - specifically, a set of microdeletions associated with clinical phenotypes (Wapner et al., 2015). It is anticipated that detailed genetic information will become accessible when NIPT is used to conduct genome-wide fetal aneuploidy detection (Bianchi et al., 2012). Research and development has progressed despite active debate about whether and how to utilize NIPT for these purposes (Allyse and Chandrasekharan, 2015; Norton et al., 2013).

Second, unlike the case for other prenatal genetic tests, industry has had an important role in the development and introduction of NIPT (Allyse and Chandrasekharan, 2015; Baudhuin et al., 2012). The stage for the introduction of NIPT was set by the small number of commercial laboratories that initially developed the technology. Each laboratory brought its own proprietary platform to market, offering a screening package to identify a unique set of genetic conditions with different sensitivities, specificities and cut-off values (Allyse et al., 2013; Mozersky and Mennuti, 2012). There is concern that the unprecedented dynamic of industry and commercial factors in the initial and continued development of prenatal genetic technologies will lead to practical and ethical issues which, in turn, will influence patients' access to NIPT in addition to the type and volume of information that can be obtained about the fetus (Agarwal et al., 2013).

The pace and context in which NIPT has emerged raises important questions about how patients and healthcare providers access information about this new screening option. Studies show that the internet is now an important source of medical information (Fox and Duggan, 2013). Currently, there is a large number of online resources available from which readers can learn about NIPT. These resources include open access peer-reviewed medical journal articles, clinical practice guidelines, public websites with evidence-based medical information, and social media sites, all of which are subject to various degrees of review (ranging from thorough to moderate, minimal, or often no quality review). This information also includes marketing materials offered by commercial laboratories that developed NIPT, which are among the lead results on an internet search on the subject (Mercer et al., 2014).

Patients are one population turning to the internet for medical information, including women who are currently pregnant or are considering a pregnancy. Studies of internet usage by select populations of pregnant women have shown that some use the internet to obtain information about the pregnancy prior to their prenatal visit and to supplement information provided by their healthcare provider after their visit (Huberty et al., 2013, Song et al., 2012); they also use it to find information about prenatal genetic testing options (Farrell et al., 2014, Farrell et al., 2015a). In addition, internet-based materials produced by commercial laboratories have become an important resource for pregnant women to gain information about NIPT (Farrell et al., 2014).

Healthcare providers are another population who utilize web-based materials to acquire knowledge and develop clinical practice patterns around the use of new tests, procedures and therapeutics (Bennett et al., 2004; Casebeer et al., 2002). Some physicians use internet-based educational materials more frequently than traditional, printed materials (Google/Hall and Partners, 2009). Web-based information developed by commercial laboratories has also become an educational resource for obstetric healthcare providers to develop and update their knowledge base about NIPT (Farrell et al., 2016). While online educational tools are an ideal mode through which to provide continuing education for physicians, there is concern about the biases that can be introduced when industry has a role in medical education (ACOG Committee on Ethics, 2012).

Despite the growth of NIPT and the role of the internet as a source of information about new tests, little is known about the content of online information produced by commercial laboratories about this new screening option. Given the availability of direct-to-consumer information on the internet about NIPT (Mercer et al., 2014) and trends in how pregnant patients and healthcare providers utilize electronic educational resources, we examined the online information presented by leading commercial laboratories regarding this new screening test. The objectives of this study were to evaluate the content of these websites and determine whether the information they presented was accurate, comprehensive and consistent, both in terms of characterizing NIPT and current clinical guidelines about its use.

Materials and methods

An internet search using the term 'non-invasive prenatal testing' in Google, Yahoo! and Bing was conducted during April 2015 to identify commercial laboratories that currently offer NIPT. At the time of the search, five US commercial laboratories were identified (Table 1).

Websites provided information targeted at two distinct consumer groups: patients and healthcare providers. Screen shots of each commercial laboratory's website were saved as PDF files and labelled with the date of capture. These images contained information visible to all readers, including patient-specific and healthcare provider-specific resources. The files were separated by content targeted at specific reader groups for combined and categorical analyses.

We utilized content analysis methodology (Morgan 1993) to evaluate the websites in our study sample. This methodology involves using a coding checklist to categorize

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