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REVIEW

Direct-to-consumer genomic testing from the perspective of the health professional: a systematic review of the literature

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Abstract Since the 1990s, there has been a rapid expansion in the number and type of genetic tests available via health professionals; the last 10 years, however, have seen certain types of genetic and genomic tests available direct-to-consumer. The aim of this systematic review was to explore the topic of direct-to-consumer genetic testing from the health professional perspective. Search terms used to identify studies were 'direct-to-consumer', personal genom*, health* professional*, physician* 'genomic, genetic' in five bibliographic databases, together with citation searching. Eight quantitative papers were reviewed. Findings indicate a low level of awareness and experience of direct-to-consumer testing in health professionals. Inconsistent levels of knowledge and understanding were also found with two studies showing significant effects for gender and age. Concerns about clinical utility and lack of counselling were identified. Health professionals specialising in genetics were most likely to express concerns. There was also evidence of perceived increased workload for health professionals post-testing. However, some health professionals rated such tests clinically useful and cited benefits such as the increased opportunity for early screening. Despite limited awareness, knowledge and experience of actual cases, we concluded that the concerns and potential benefits expressed may be warranted. It may be useful to explore the attitudes and experiences of health professionals in more depth using a qualitative approach. Finally, it is essential that health professionals receive sufficient education and guidelines to equip them to help patients presenting with the results of these tests.

Keywords Direct-to-consumer · Genetic test · Genomic test · Health professionals · Systematic review

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Introduction

Rapid advances have taken place in the field of healthcare genetics since the 1990s, resulting in an expanding range of genetic and genomic tests available for use by health professionals (Burton 2011). These range from diagnostic tests for single-gene disorders (such as cystic fibrosis) to pre-symptomatic (or predictive) tests that can identify mutations in genes strongly associated with the onset of certain diseases such as Huntington disease. A more recent development, susceptibility testing, offers the patient an opportunity to become aware of their genetic predisposition to some common diseases (National Human Genome Research Institute 2011). Susceptibility tests are generally based on findings from genome-wide association studies, but there is some controversy about their validity and clinical utility due to the weak nature of many of these associations (Hauskeller 2011; Hennen et al. 2010; Visscher et al. 2012), and for that reason, health professionals may be unwilling to order them on behalf of patients.

There is a range of genetic tests available via the Internet. While some companies market tests that include those for characteristics such as athletic ability and bitter taste perception, others focus on health-related products such as

carrier testing, pharmacogenomic testing and testing for susceptibility to common diseases. Several companies currently offer susceptibility tests direct to consumer (DTC), for example, 23andMe (https://www.23andme.com/ accessed 10 January 2013) and easyDNA UK (http://www.easydna.co.uk/, accessed 10 January 2013), the latter offer predisposition testing for 25 diseases and conditions including atrial fibrillation, multiple sclerosis, cancers, and type 1 and 2 diabetes. Both of these companies allow consumers to purchase tests without first consulting a physician, although the latter stress the importance of both pre- and post-test counselling. Increasingly, however, companies are only offering certain genetic tests via a physician (Borry et al. 2011). In some cases, potential consumers are required to consult a physician (either their own or one nominated by the company) prior to ordering, and results are sent to a physician rather than the consumer. Genetic counselling may be provided by counsellors employed by or directly linked to the company (https://www.counsyl.com/, accessed 10 January 2013).

The availability of DTC genetic tests has implications for health services, as there is potential for the workload of health professionals to increase commensurate with test uptake. In order to respond to requests from patients for guidance and help in interpreting test results, they will require adequate knowledge of the topic to enable them to advise their patients following such a test. In studies that related to DTC genetic tests from the perspective of the consumer (Bloss et al. 2011; Gollust et al. 2011; McGuire et al. 2009), it was apparent that the knowledge, experience and attitudes of health professionals are likely to play an important part in the future expansion (or otherwise) of DTC testing for susceptibility to a range of diseases and that consumers wish to have health professional advice about the results of DTC tests. While there is a body of evidence on the informational content of websites supplying DTC genetic tests and on the effect that DTC advertising of such tests has on consumers and health professionals (for example, Einsiedel and Geransar 2009; Lachance et al. 2010), we were unable to identify a systematic appraisal of studies that include the perspectives of health professionals.

The aim of this systematic review was therefore to explore the views, attitudes and experience of health professionals (HCP) with respect to direct-to-consumer genetic testing. The review has the following objectives:

- To identify the level of awareness of DTC genetic testing in HCPs;
- To explore the level of knowledge that HCPs have about DTC genetic tests and the companies that provide them;
- To describe the attitudes of HCPs to this type of test;
- To identify what HCPs perceive as the potential benefits and risks; and
- To identify the perceived role of HCPs in DTC genetic testing.

Methods

Conducting a systematic review is a process that is designed to enable researchers to gather comprehensive information on a topic, to weigh up the evidence and synthesise it to form conclusions (Polit and Beck 2006). We used a rigorous search strategy, using inclusion and exclusion criteria and appraised the quality of the papers, as advocated by the Centre for Reviews and Dissemination (2008). An integrative approach to this systematic review was used to ensure qualitative and quantitative studies could be included.

Search terms

The following search terms were used:

> 'Direct-to-consumer' OR personal genom* AND health* professional* OR physician* AND genet* OR genom* anywhere in the text of the paper.

Limitations

Papers were restricted to those published in English between January 2001 and July 2012, as HCPs were unlikely to be aware of DTC testing prior to 2001.

Inclusion and exclusion criteria

Primary research papers and systematic reviews in which studies included empirical data on the attitudes, views and opinions of health professionals towards DTC genetic tests were eligible for inclusion. A hand search was conducted of the full reference lists of all papers included in the review.

Papers were excluded if they: reported research related to use of DTC tests by consumers, focussed primarily on direct-to-consumer marketing or advertising of genetic tests, related to direct-to-consumer nutrigenomic tests or ancestry testing. Opinions, commentaries and ethics papers were also excluded. Decisions about inclusion or exclusion of papers were reached through discussion and consensus between three of the authors.

It should be noted that there was a need to distinguish between papers relating to DTC advertising or marketing of genetic tests and to the DTC provision of such tests. For example, Mouchawar et al. (2005) and Myers et al. (2006) investigated the effect of DTC marketing and advertising of BRCA testing for breast and ovarian cancer risk on potential patients and health professionals, but the company owning

the patent for these tests was not selling directly to the public. Papers such as these were therefore excluded.

Information sources

The databases used were CINAHL, PubMed, PsycINFO, Embase and Medline.

Quality appraisal

The quality of the papers was assessed by three of the authors using the Kmet tool for appraising quantitative and qualitative research (Kmet et al. 2004). For example, in the checklists for assessing the quality of studies, questions include whether subject (and comparison group, if applicable) characteristics were sufficiently described and whether data collection methods were clearly described and systematic.

Using this tool, a score of between 0 and 1 was assigned to each paper based on a series of questions related to the type of study. Scores ranged from 0.66 to 0.94, and all papers were therefore considered to be of adequate quality for inclusion. The quality scores are provided in Table 1 as an indicator of the rigour of each study.

Data collection and synthesis

Although quantitative methods were used for each of the eight papers, it was not considered appropriate to conduct a meta-analysis due to the disparity in study populations and research questions; we therefore undertook a narrative analysis of the papers. The papers were read in depth, and the main features of each were summarised and presented in a table (Table 2). Further data were extracted from the findings in the form of basic codes. The codes were scrutinized by two of the authors and grouped into categories. Major themes were identified using thematic analysis (Braun and Clarke 2006), and the findings are presented under these themes.

As this was an inductive thematic analysis, we present the themes that emerged from data analysis rather than restricting the findings to those outlined a priori in the objectives. Table 1 shows the relevant themes identified from each paper.

Findings

Description of the studies and participants

A total of eight papers were identified for this review. These papers are diverse in terms of participants and the countries in which the studies were conducted. Survey methods were used in all studies, four online (Giovanni et al. 2010; Hock et al. 2011; Haga et al. 2011; Brett et al. 2012), one via mail (Ohata et al. 2009), one on paper (Mai et al. 2011) and two with a choice of online, fax or mail (Powell et al. 2011). Five studies were conducted in the United States (US) (Giovanni et al. 2010; Haga et al. 2011; Hock et al. 2011; Powell et al. 2012, 2011), one in Greece (Mai et al. 2011), one in Australia (Brett et al. 2012) and one in Japan (Ohata et al. 2009). For the five US studies, genetic counsellors (Hock et al. 2011), genetic counsellors and medical geneticists (Giovanni et al. 2010) and physicians (Powell et al. 2011, 2012; Haga et al. 2011) were recruited. Authors of the Australian study (Brett et al. 2012) recruited genetic counsellors and clinical geneticists. Participants in the Greek study (Mai et al. 2011) were physicians. The study from Japan (Ohata et al. 2009) had participants termed ‘general practitioners’ and ‘clinical geneticists’, but the definition of these terms is perhaps not universal, and care had to be taken when interpreting and synthesising the findings for this review. For clarity, the definitions of participants in the studies are as follows:

- Geneticist: A geneticist is defined as a medical doctor trained as a specialist in genetics, or a qualified genetic counsellor or nurse

Table 1 Summary of themes identified in this systematic review

	Awareness, knowledge and experience	Beliefs and opinions	Downstream costs and referrals	Genetic counsellors’ opinions of their roles
Brett	√			
Giovanni		√	√	
Haga	√			
Hock	√	√		√
Mai		√		
Ohata	√	√		
Powell et al. 2011	√	√	√	
Powell et al. 2012	√			

Table 2 Details of papers identified from the systematic review

Reference	Purpose of study	Methodology and data collection method	Sample and size	Method of analysis	Findings most relevant to this review	Quality including Kmet score and any limitations
Brett et al. (2012)[a] (AUS)	"To determine the reported frequency of individuals presenting to genetics services after undertaking DTC genetic testing, to explore the opinions and experiences of genetic health professionals regarding DTC genetic testing" (p2) ("and to explore the perceived opinions and experiences of clients who have undertaken DTC genetic testing".)	Quantitative;online survey	Population: members of the Human Genetics Society of Australia (HGSA) *n*=130 (genetic counsellors) *n*=38 (clinical geneticists)	Descriptive statistics. Chi-square tests to identify any difference between professional groups. Chi-square tests to identify relationships between firm opinions	Respondents had mixed opinions regarding DTC genetic testing (and a third did not have firm opinions). The majority did not consider DTC testing useful for clients who wanted anonymity, were curious or geographically isolated (but genetic counsellors more likely than clinical geneticists to consider it useful for anonymity or geographical isolation). Only 7 % were confident in accurately interpreting and explaining the results. Eleven percent had had one or more client referred to them following DTC genetic testing.	0.78; this was a well conducted study but would have benefited from some qualitative data concerning the opinions of health professionals. The authors acknowledge that the design of the survey could be improved by the addition of a five-point Likert scale rather than the use of 'possibly' responses.
Giovanni et al. (2010) (US)	"To query clinical geneticists about their experience with individuals who consulted them after DTC genetic testing." (p817)	Quantitative;online survey	Members of the National Society of Genetic Counselors (NSGC), the Adult Genetics Special Interest Group and the American College of Medical Genetics (ACMG)n=121 genetic counselors *n*=6 medical geneticists *n*=6 other healthcare providers	Descriptive statistics of questionnaire responses	Over 50 % of the health care providers considered the DTC tests to be useful (but note that of these, 85 % considered that BRCA (breast cancer susceptibility gene) testing was useful). NB. This is only a pilot study, numbers are small, response rate was poor and only 41 % were SNP (single-nucleotide polymorphism) testing (others were single gene). The study also looked at 'downstream costs of further healthcare referrals'.	0.66; the poor recruitment rate (3.3 %) and strategy (no incentives or reminders following the email invitation) resulted in only 22 eligible participants in the study by Giovanni et al. (2010). However, of these 22, six health professionals had seen patients whose tests were from companies that only provide tests via health professionals, so cannot be considered as DTC tests
Haga et al. (2011) (US)	"To assess physician attitudes and uptake of genomic risk profiling among an 'early adopter' practice group." (p835)"	Quantitative;online survey.	Population: physicians in the MDVIP network *n*=157	Descriptive statistics for each question; Fisher's exact tests for association between two categorical response variables. Regression analysis to identify predictor variables.	The odds of having ordered personal testing were over tenfold higher for those who felt well-informed about genomic risk testing. The odds of ordering testing for their patients were over eight-fold higher among those who had ordered tests for themselves. Clinical utility was a concern for both physicians who had ordered tests and those who had not.	0.83; in the study by Haga et al. (2011), participants were physicians who were part of a collaboration with Navigenics in 2008; these physicians were offered free genomic profiling for themselves and discounted prices for their patients, and were also given access to four online educational modules on genomic risk. We consider that this renders the findings less robust and less generalizable.
Hock et al. (2011) (US)	"To assess genetic counselors' experience, knowledge, and beliefs about DTC genetic testing " (p326)	Quantitative; online survey	Population: members of the National Society of Genetic Counselors (NSGC) (US) *n*=312	Chi-square and Mann–Whitney *U* test to assess differences between sample population and the NSGC 2008 Professional Status survey. Comparison between groups re knowledge scores using Welch's	Limited experience of DTC testing: e.g. 81 % stated that the no. of times patients had raised the issue of DTC testing in the last 2 yrs was<2. Although 75 % had visited a DTC website, 15 % or less suggested it to patients or	0.88; a copy of the survey questionnaire was not included in this study, so it was difficult to evaluate whether the results had been fully reported. The authors acknowledge that there was some ambiguity in the

Table 2 (continued)

Reference	Purpose of study	Methodology and data collection method	Sample and size	Method of analysis	Findings most relevant to this review	Quality including Kmet score and any limitations
				t-tests. Remainder was descriptive statistics. Quotations used to illustrate responses to open-ended questions.	referred patients. Low level of knowledge of DTC testing-for example, what tests are available; those genetic counselors who worked or consulted for DTC companies scored significantly higher on knowledge section ($p<0.001$) Opinions divided on whether genetic testing should be limited to clinical setting, but 56 % agreed that it is an acceptable method if counselling is provided.65 % disagreed that individuals can obtain adequate information on the Internet. More agreed with statements about risk than agreed with statements about benefits of DTC testing.55 % felt they should be knowledgeable about DTC testing, 48 % to be able to interpret DTC test results. Participants expressed the fact that the quality of DTC companies varies, and that their acceptance of DTC services depended on many factors such as availability of counselling.	design of the survey with reference to the definition of a DTC test and this may have confounded their findings.
Mai et al. (2011) [a] (GREECE)	To ascertain the views of the general public and physicians on the genetic testing services currently available in Greece; to understand both the wishes and needs of (the general public and) physicians with regard to the genetic testing industry and identify regulatory deficiencies and gaps in the existing legal provision.	Quantitative; cross-sectional survey.	Population: physicians attending a national Greek medical conference in May 2010n=496	Frequency tables and chi-square tests. Contingency tables to display relationship between two or more variables, using chi-square test. Probabilities of <0.05 considered statistically significant.	Only a small proportion (12.7 %) of physicians was in favour of direct access genetic testing.	0.66 Using the Kmet appraisal criteria, we considered that the study design would have been improved by collecting qualitative data as well as quantitative. The conclusions were not were not fully supported by the findings.
Ohata et al. (2009) (JAPAN)	To identify problems associated with the expansion of 'new' genetics service, in particular, direct-to-consumer.	Quantitative; survey	Population: physicians from the Medical Association of Kanagawa Prefecture, members of the Japan Society of Human Genetics and the Japanese Society for Genetic Counseling $n=1145$ physicians $n=294$ clinical geneticists.	Descriptive statistics and t-tests for associations.	Awareness of DTC genetic testing: 40 % GPs, 70 % clinical geneticists. GPs rated the benefits of DTC significantly more highly than clinical geneticists, and the latter were significantly more concerned about the risks. In particular concerns were re reliability of results, provision of information and counselling, understanding of results.	0.77; similarly to other studies, this study would have benefited from the addition of some qualitative data. The authors acknowledge that because the data was collected two years prior to publication, in the early days of DTC testing, their findings may not be robust.
Powell et al. (2011) (US)	"To assess primary care physicians' (PCPs') awareness, experience, opinions and preparedness to answer patients' questions regarding direct-to-consumer genetic testing." (p1)	Quantitative; survey: choice of online, fax or paper	Population: Members of the North Caroline Medical Society (NCMS) $n=382$	Descriptive statistics for personal characteristics and survey responses relating to self-reported awareness, experience with patients, opinion and preparedness. Bivariate associations calculated using cross tabulations, and odds ratios to	38.7 % of respondents were aware of, and 15 % felt prepared to answer questions about DTC tests. Age (50 or older) was a predictor of awareness of DTC testing, and male providers more likely to be prepared to answer questions about DTC. Among respondents who were aware, family practitioners	0.94; a limitation of this study was the low response rate (16.2 %)

Table 2 (continued)

Reference	Purpose of study	Methodology and data collection method	Sample and size	Method of analysis	Findings most relevant to this review	Quality including Kmet score and any limitations
				explore the strength of the associations. Model produced using step-wise forward regression.	more likely than internists to think DTC testing was clinically useful. 18 % of those who were aware had patients who had questioned them or brought in results from DTC tests.	
Powell et al. (2012) (US)	"To assess the education needs of North Carolina PCPs about direct-to-consumer (DTC) genetic testing. Other aims were to ascertain: (1) PCPs' preference for delivery of educational materials; (2) barriers to PCPs' participation in a continuing education program; (3) PCPs' preference for topics to include in an educational program on DTC genetic testing." (p1)	Quantitative; survey	As Powell (2011) paper above; same study.	Descriptive statistics for personal characteristics and survey characteristics such as self-reported preparedness, desire to learn more. Bivariate associations calculated using cross tabulations. Step-wise forward regression analysis used to refine model.	85 % of respondents felt unprepared to answer questions about DTC tests (see above). Seventy-four percent wanted to learn about DTC genetic testing. PCPs who felt either unprepared to answer patient questions ($p=0.01$) or that DTC testing was clinically useful ($p=0.00$) were more likely to want to learn about DTC genetic testing.	0.78; the same limitation as that for Powell et al. (2011) applies.

[a] In these papers, participants included consumers/member of the public as well as health professionals; but in this review, we report only the findings relating to the health professionals

- General practitioner/family doctor/family physician: In Europe, the first term describes physicians working in primary care (i.e. non-specialists) (WONCA Europe 2002). The equivalent term in the US would be family physician (http://www.aafp.org/online/en/home.html, accessed 10 January 2013). However, in Japan, the term primary care physician would be used (http://www.primary-care.or.jp/about/aboutus_eng.html, accessed 10 January 2013). In Japan, the term 'general practitioner' appears to include physicians and surgeons working in hospitals, clinics and private practice.

These distinctions are important when discussing the main findings of the studies in this review. In the context of this paper, for clarity, we will refer to any doctors working in a hospital, clinic or private practice as 'specialist doctors' and those working in family practice or the community as 'family doctors'. We will now describe the main themes that emerged from the eight papers. We identified two major themes ('Awareness, knowledge and experience' and 'Beliefs and opinions') and two minor themes ('Downstream costs and referrals' and 'Genetic counsellors opinions on their role').

Awareness, knowledge and experience of DTC genetic testing

There appears to be a variable level of awareness of DTC genomic testing among physicians and surgeons working both in hospital and primary care or private settings (Powell et al. 2011; Ohata et al. 2009). In a US study, Powell et al. (2011) found that 61.3 % of respondents were unaware of DTC genetic testing, as were 62 % of specialist doctors and 31.6 % of clinical geneticists in the Japanese study (Ohata et al. 2009). In another US study, Haga et al. (2011) found that 90 % of physicians in the MDVIP network were aware of DTC testing, although only 42 % felt well-informed about it. In the US, the most common sources of knowledge were medical or scientific journals (35.1 %), television (33.1 %), newspaper articles (28.4 %) and the Internet (27.0 %) (Powell et al. 2011). In Japan, however, 56.6 % of specialist doctors (as defined above) were made aware of DTC genomic testing via TV, newspapers or magazines, followed by 30.1 % from scientific meetings or journals and 21 % via the Internet (Ohata et al. 2009). In contrast to non-geneticists, clinical geneticists in Japan were most likely to gain their information from the Internet (43.2 %), TV, newspapers or magazines (38.7 %), or scientific meetings or journals (34.7 %) (Ohata et al. 2009). Interestingly, patients were also mentioned as a source of awareness: for 21.6 % of health professionals in the US (Powell et al. 2011) and for 4.7 % of non-geneticists and for 6.0 % of geneticists in Japan (Ohata et al. 2009). However, a minority of health

professionals (13.5 % in the US, 11.7 % of non-geneticists and 7 % of geneticists in Japan) stated they had been made aware by direct contact from DTC companies (Ohata et al. 2009; Powell et al. 2011). Powell et al. (2011) found a strong positive association between age of the health professional and his or her level of awareness; respondents over the age of 50 years were significantly ($p<0.05$) more likely to be aware of DTC genetic testing than those aged 40 years and younger. The demographics of participants were provided in the paper by Ohata et al. (2009), but no analysis of the effect of age, gender or workplace was given. Powell et al. (2011) found no association between workplace setting or gender and awareness.

In a study designed to assess the knowledge and beliefs of genetic counsellors, Hock et al. (2011) found inconsistent levels of knowledge about DTC testing; the mean number of questions correctly answered was 8.8 (SD 4.2) of 20 knowledge questions. There were high levels of 'don't know' answers, for example, more than 50 % of respondents either did not know or answered incorrectly when asked about diseases that could be included in a DTC test. Unsurprisingly, it was noted that genetic counsellors working for DTC genetic testing companies scored significantly ($p<0.001$) higher on these knowledge questions with a mean score of 15.7, compared with a score of 8.6 for those not employed by DTC companies.

This finding of a low level of HCP knowledge was supported by Brett and colleagues (2012), who recruited 130 genetic counsellors and 38 clinical geneticists in Australia, and found that only 7% were confident in their ability to interpret and explain the results of DTC genetic tests.

In the study by Powell et al. (2011), the authors found that the majority (85 %) of their primary care physician participants did not feel prepared to answer patients' questions on DTC testing. They found significant effects ($p<0.05$) for gender and age; male physicians were twice as likely to feel prepared for questions, as were primary care providers aged 51 years or over. There was also a positive correlation between awareness and perceived preparedness (Powell et al. 2011). In a later paper, Powell et al. (2012), using data from the same group of participants, found that 74 % wanted to learn about DTC genetic testing and that those who felt either unprepared to answer patients' questions or considered DTC testing clinically useful, were more likely to want to learn about the subject. Ohata et al. (2009) considered that the general practitioners in their study were rarely involved in medical genetics or genetic services in their everyday practice. Despite being aware of DTC genetic services, 81.1 % of primary care physicians in the US study had not discussed such tests with patients or seen a patient who had received such a test (Powell et al. 2011). However, 28 participants (18.9 %) did have at least one patient who asked about DTC testing, and five had at least one patient who brought in DTC results for discussion. Hock et al. (2011), in their study of genetic counsellors, stated that 46 % of respondents had discussed DTC testing with patients who had introduced the subject, but in the majority of these cases (63 %) this involved only one or two patients. Despite a high level of awareness, as evidenced by 75 % of these participants having visited a DTC genetic testing website, only 15 % suggested DTC testing to patients, 11 % had referred a patient to a specific DTC testing website, and 8 % had suggested that a patient search online for DTC genetic testing (Hock et al. 2011). We considered that the high level of awareness indicated a certain level of knowledge but that it also revealed the counsellors' attitudes to DTC testing, as described in the next section.

Beliefs and opinions about DTC testing

Data on beliefs and opinions of DTC testing were identified from each of the studies, although each had a different focus. We have included views on the clinical utility and validity of such tests, together with ethical issues in this section. In a study investigating onward health care referrals following DTC testing, Giovanni et al. (2010) found that 52.4 % of healthcare providers (over 90 % of whom were genetic counsellors) considered the DTC test about which their patient had consulted them as useful. It should be noted, however, that 20 % of the patients had their tests via companies that only offered tests via a healthcare provider. In cases of BRCA1/2 testing, this was considered clinically useful in 85.7 % of cases. Of the remaining tests about which consumers sought advice, 64.3 % were not considered clinically useful by the HCP.

In a study conducted in Greece (Mai et al. 2011), only 12.7 % of physicians were in favour of what was termed 'direct-access testing' (p559); this definition included access via pharmacies or private genetic laboratories. Of those against direct-access testing, 89.7 % believed that referrals should be made by physicians. In a US study by Powell et al. (2011), almost half of the respondents (42.6 %) who were aware of DTC testing considered it clinically useful in management of their patients' health, although the majority of these (84.7 %) only rated it as 'somewhat useful'. Of those who were aware of DTC testing, 38.8 % considered it very likely or likely to influence patient care. Benefits cited by the healthcare providers as making DTC testing useful included the ability to offer screening tests at an earlier age and more frequently, based on the DTC test results. Respondents to this study, however, did have some concerns about DTC testing; these included increased patient anxiety (87.1 %), incorrect interpretation of results by patients (85.1 %), misleading advertisements (85.1 %) and questionable clinical utility (81.8 %).

Those who did not consider DTC testing clinically useful cited the following reasons: lack of guidelines to reduce any identified risk for many diseases (80 %); problems with interpreting how the DTC results could be integrated into patient care (58.8 %) and patient anxiety (51.8 %), while 35.3 % stated that they would not change a patient's management based on DTC test results. Other reasons (18.8 %) included lack of clinical usefulness, lack of accuracy of test results and concerns about the effect on the patient's future health insurance. In contrast, Hock et al. (2011) found that 92 % of genetic counsellors perceived that patients were at risk of receiving misinformation.

Powell et al. (2011) reported that, of five respondents who had patients who had sought advice about results, four considered that DTC testing was not clinically useful. They also found that specialty and gender were predictors of respondents' opinions on the clinical usefulness of DTC testing, with family doctors and males significantly ($p<0.05$) more likely to think DTC was clinically useful.

In the Japanese study (Ohata et al. 2009), participants aware of DTC testing were given a list of 11 statements and asked to score their agreement with them on a scale ranging from 1 to 4. The mean scores of non-geneticists were significantly different ($p<0.001$) from those of clinical geneticists with respect to benefits and some of the risks of DTC testing. The non-geneticists expressed more positive views on the benefits such as convenience, the promotion of preventive medicine, provision of personalized services and confidentiality of information (all $p<0.001$). The clinical geneticist group were significantly more concerned about the risks: reliability of test results, provision of information/counselling, understanding of results (all $p<0.001$) and advertising ($p<0.01$). In a study of the knowledge and beliefs of genetic counsellors (Hock et al. 2011), the perceived risks appeared to outweigh the benefits. Over 90 % of participants perceived 'receiving misinformation' and 'a false sense of security from a negative test result' as risks, with scores for perceived benefits; 'raising awareness about genetics' (48 %) and 'learn about genetic conditions they may be at risk for' (47 %) much lower. Also of interest is that, for many of these perceived risks and benefits, participants expressed a neutral opinion (for example, for the risk of 'psychosocial harm', 61 % agreed that it was a risk, with 32 % neutral and 7 % who disagreed). Similarly, there were neutral scores for benefits such as 'raised awareness about genetics' (29 %), 'learn about genetic conditions they may be at risk for' (23 %) and 'stimulates individuals to facilitate family discussions' (33 %).

Downstream costs and referrals subsequent to DTC testing

One of the possible implications of increased public awareness of DTC genetic testing is the effect this will have on the workload of health professionals and the associated costs of any increased screening, diagnostic tests and onward referrals subsequent to these DTC tests (McGuire and Burke 2008; McGuire et al. 2009). Giovanni et al. (2010) recruited from three different groups of health professionals including genetic counsellors and medical geneticists in the US. Only 22 of the 133 participants had seen patients following a DTC test; these participants were asked about referrals made as a result of the DTC test result; seven out of the 22 respondents made no onward referrals, but of the remaining 15, 11 (73.3 %) made one referral, two (13.3 %) made two and two (13.3 %) made three or more. Four referrals were made to breast care specialists or surgeons, six to geneticists or another type of genetic counsellor and two to radiologists (four were classed as 'other' with no further detail). In addition to this, various diagnostic or screening tests were made as a result of the DTC genetic testing; these included further genetic testing, mammography, CA-125, CT or MRI of chest or abdomen and PSA.[1] The authors estimated the cost of subsequent follow-up care ranged from $40 to $20,604 for the highest cost case. None of the other papers specifically investigate this aspect of DTC testing, but the findings of Powell et al. (2011) (that 38.8 % of health professionals who were aware of DTC testing considered that the test results would influence patient care) may indicate there will be additional downstream costs.

Genetic counsellors' opinions of their roles in DTC genetic testing

Although this topic was only identified in one paper, we regard it as an important and distinct theme. Hock et al. (2011) found that genetic counsellors perceived they had an obligation to be knowledgeable about DTC testing (55 % agreement with this statement) for their patients and to interpret test results (48 % agreement). There appeared to be a reluctance to suggest DTC testing for patients (only 4 % agreement). However, under certain circumstances, a referral would be acceptable; for example, if there was concern about genetic discrimination, 16 % agreed that they would refer for DTC testing and 55 % gave a neutral answer. If there was concern about anonymity for the patient, 19 % of respondents said they would consider referral and 57 % gave a neutral answer. In addition, 29 % agreed that, if a patient was unable to access genetic services for geographical reasons, they would consider referral for DTC testing; 60 % gave a neutral answer to this question. As well as being asked specific questions, respondents were provided with some open-ended questions that provided more detailed information on their views about their role in relation

[1] CA-125, cancer antigen-125; CT, computerised tomography; MRI, magnetic resonance imaging; PSA, prostate-specific antigen

to DTC testing. Respondents expressed concern about the lack of availability of genetic counselling from some DTC companies. Some also expressed the view that genetic counsellors should have more involvement in the development of DTC services.

Discussion

The aim of this review was to explore the topic of DTC genetic testing from the health professional perspective. Although this is a subject about which there has been much comment and opinion published, indeed concern expressed (Howard and Borry 2008; Hunter et al. 2008; Loud 2010; Thrush and McCaffrey 2010; Wade and Wilfond 2006), there appears to have been very little primary research with health professionals. Of the eight papers we did identify, three focussed mainly on genetic counsellors and five on physicians.

It is clear from the evidence in this review that not only can the views of genetic counsellors and physicians involved in the clinical genetics field differ from those of other health professionals, but also that there is inconsistency in the level of knowledge and awareness in both groups. We would therefore like to summarise the main positive and negative views and outcomes we have identified from these papers.

Perceived negative aspects of direct-to-consumer genetic testing

Factors such as limited knowledge and experience of DTC genetic testing may have contributed to the reservations expressed by genetic counsellors (Hock et al. 2011; Brett et al. 2012)and by other health professionals such as specialist doctors, family doctors and clinical geneticists (Ohata et al. 2009; Powell et al. 2011). Concerns about the quality of information on DTC websites and the lack of counselling, together with issues such as reliability of results and clinical utility, were also identified (Hock et al. 2011; Ohata et al. 2009; Powell et al. 2011). It is interesting to note that concerns about the clinical validity and reliability of DTC test results were not prominent in the majority of these studies, especially as there is evidence of disparity in the risk calculations between DTC companies (Imai et al. 2011). It appeared, however, that the more closely a health professional worked to the specialty of genetics, the more likely it was that they would have such concerns (Ohata et al. 2009).

The other main finding that could be considered as negative from this review is the potential increased workload for health professionals and the need for them to ensure that their level of knowledge of genetics is adequate to answer questions from patients who have undergone DTC testing. While there is some fear that the drain on health resources will increase, very recent research undertaken in one health insurance organisation (Reid et al. 2012) indicated this was not the case. However, further evidence is required, especially in the context of public health services. It is not clear whether the lack of preparedness identified in doctors (Powell et al. 2011) resulted from a lack of knowledge or a negative attitude to DTC testing; the authors assessed participants' opinions on the risks and benefits of DTC genetic testing, but not specifically their knowledge. We have reported evidence on knowledge of DTC testing (Hock et al. 2011; Brett et al. 2012) obtained by asking specific questions; this should be distinguished from perceived confidence of knowledge on the topic, as reported by Haga et al. (2011). The educational implications of increased awareness of and use of DTC testing have been discussed in the literature (Caulfield et al. 2010); there is also evidence of a low level of genetics knowledge among health professionals generally (Guttmacher et al. 2007; Baars et al. 2005; Houwink et al. 2011).

Perceived positive aspects of direct-to-consumer genetic testing

There were some perceived positive aspects of DTC identified in this review. There appeared to be a consensus view that DTC genetic testing was more acceptable if it could be offered alongside the services of a genetic counsellor, both pre- and post-test. Although the counsellors in the study by Giovanni et al. (2010) were equally divided on whether genetic testing should be limited to a clinical setting, over half of them agreed that it was acceptable if counselling was provided. This finding is supported by previous research (Wilde et al. 2011; Gray et al. 2011; Perez et al. 2011) that there was a preference among consumers to access genetic tests via a health professional. In one US study, among the health professionals who were aware of DTC testing, 43 % cited benefits such as the ability to offer relevant screening tests at an earlier age and to offer more frequent screening as appropriate (Powell et al. 2011). Family doctors were three times as likely to consider DTC testing clinically useful as those practising general medicine (Powell et al. 2011). Opinion on the clinical utility of a DTC genomic test is controversial; however, a recent study concluded that, in cancer risk assessment, evaluation of family history is the tool of choice to evaluate an individual's cancer risk until there is better concordance between genome-wide association studies and family history-based risk assessment (Heald et al. 2012).

Implications for professional education

It is generally acknowledged that knowledge of genetics in health professionals is low and that there is a need for

genetic education to prepare non-genetic health professionals for the advances in applied health genetics (that will eventually be translated into general health care) (Baars et al. 2005; Burke and Kirk 2006). In our review, this viewpoint was confirmed by three studies, not only in relation to genetic education, but in particular the need for knowledge and education on personal genomics, often provided in the form of DTC testing (Haga et al. 2011; Powell et al. 2012; Brett et al. 2012). We did not, however, include education as a theme, as it was the authors of these papers who inferred the need for education (rather than this being reported as a finding), and this was therefore mentioned in the "Discussion" sections of the papers. In view of the time constraints imposed on many health professionals, it will be important to provide any new educational resources in an appropriate format and with a suitable provider. Haga et al. (2011) suggest that there may be a role for genetic counsellors in providing education on DTC testing for primary care physicians, but this is questionable in view of evidence identified in our review (Brett et al. 2012; Hock et al. 2011). Resources favoured by primary care physicians included continuing medical education courses, medical journals, professional medical meetings, trusted Internet websites and educational programs offered by DTC companies (Haga et al. 2011; Powell et al. 2012). It has been suggested, however, that primary care physicians are "just in time learners who are driven by their need for information at a specific point in time" (Powell et al. 2012, p474), and therefore resources that are immediately accessible when a patient makes an enquiry may be most suitable for them.

The challenges faced by health physicians are summed up in a recent commentary (Kroese 2012) stating the importance of ensuring that DTC results can be interpreted accurately and that the user (individual consumer or health professional) understands how to apply them, where there is clearly demonstrable utility for health care (Borry 2010).

Limitations of this review

Although we decided to include all eight papers in this systematic review, it should be noted that there are some methodological weaknesses that may render some of these studies less robust. We have listed these limitations in Table 1.

In addition to this, two of the studies may have benefited from a qualitative approach. Participants in studies by Powell et al. (2011) and Ohata et al. (2009) were presented with statements based on previous surveys, and it would have been useful to have obtained further data using a qualitative approach, as this is an appropriate method when exploring attitudes and experiences (Morse and Field 1996).

Kolor et al. (2009), however, reporting the results in a large-scale US national study found that 42 % of health professional respondents were aware of DTC testing, 42 % of these had been asked questions about DTC testing, and 15 % had been presented with DTC test results by a patient. It is possible that the findings in the report by Kolor et al. (2009) are more representative of the overall situation in the US, as the study by Powell et al. (2011) was only conducted in one state. However, the report by Kolor et al. (2009), although identified in the systematic search, was excluded due to the fact that it was a letter and did not include sufficient material about the research method to justify inclusion.

Overall, it is difficult to draw conclusions about health professionals' views on DTC testing, as the level of awareness of DTC testing in the studies in this review was inconsistent but generally low, and so few respondents have had direct experience with DTC testing; this inevitably means that responses are based not on experience but on judgements of hypothetical situations. It is pertinent, however, to note that similar concerns have been expressed in other literature published by professionals from a range of backgrounds, for example, ethics (Caulfield et al. 2010; Howard and Borry 2008), law (Tamir 2010; Vashlishan Murray et al. 2010), public health (Khoury et al. 2009) and clinical genetics (Li 2011).

Conclusions

There are three main conclusions from this systematic review. Firstly, it is clear that, despite interest and concern in the arenas of research and genetics, awareness and knowledge of DTC genetic testing among health professionals is variable. Those who are aware of it have expressed reservations about its use; in particular, concerns about the availability of appropriate information and counselling, the clinical validity and utility of some of the genetic tests offered direct to the consumer and potential problems in the interpretation of results by both consumers and health professionals. However, some of the data included in this review were collected up to 5 years ago, and awareness may have changed since that time.

Secondly, some benefits have been expressed, for example, the opportunity for more appropriate and frequent screening and testing following DTC tests. However, the low number of health professionals with direct experience of such tests recruited to these studies renders this finding less robust. We have identified no evidence to support these views, and future research is needed to determine whether there will be specific benefits arising from DTC testing in this context.

Finally, we consider that as well as further exploring the attitudes and experiences of health professionals to DTC testing using a qualitative approach, it is important that they

are provided with the necessary education and knowledge, together with professional guidelines on how to advise and help patients who consult them following a DTC test. In particular, there are implications for medical geneticists and genetic counsellors, as they are the professional group most likely to be seeing such patients in increasing numbers following onward referral from primary care physicians. It is essential that continuous professional development opportunities are used to ensure that genetic counsellors in practice are familiar with the output of these products and are able to support patients in interpreting and utilising them for the benefit of their personal and family health.

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