

Quality and use of consumer information provided with home test kits: room for improvement

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Abstract

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Accepted for publication

2 June 2012

Keywords: consumer information,
quality assessment, self-test,
self-testing

Background Diagnostic self-tests (tests on body materials that are initiated by consumers with the aim of diagnosing a disorder or risk factor) are becoming increasingly available. Although the pros and cons of self-testing are currently not clear, it is an existing phenomenon that is likely to gain further popularity.

Objective To examine consumers' use of and needs for information about self-testing, and to assess the quality of consumer information provided with home test kits, as perceived by consumers and as assessed using a checklist of quality criteria.

Methods A cross-sectional Internet survey among 305 self-testers assessed their use of and needs for information and their perception of the quality of consumer information provided with self-test kits. A meta-search engine was used to identify Dutch and English consumer information for home diagnostic tests available online at the time of the study. The quality of this consumer information was evaluated using a checklist of quality criteria.

Results The consumers' information needs were in line with the most frequently used information, and the information was perceived as being of moderate to good quality. The information was mostly in agreement with clinical practice guidelines, although information on reliability and follow-up behaviour was limited. Approximately half of the instruction leaflets did not include information on the target group of the test.

Conclusions Although generally of moderate to good quality, some aspects of the information provided were in many cases insufficient. European legislation concerning self-tests and accompanying information needs to be adapted and adhered to more closely.

Introduction

Diagnostic self-tests have become available for over 25 conditions, ranging from infectious diseases like HIV to cardiovascular risk factors such as detecting high cholesterol.¹ Self-tests are defined as *in vitro* tests on body materials such as blood, urine, faeces, or saliva that are initiated by consumers to diagnose a particular disorder or risk factor.²

The use of self-tests is in line with current views on patient autonomy, as it implies that consumers can test themselves for health conditions without the need to consult a doctor first.^{1,3} When using a home self-test, consumers are the only ones responsible for performing the test and interpreting its result, and for their own follow-up behaviour. On the basis of these distinct responsibilities, we can distinguish four phases within the home self-testing process, namely (i) the decision process preceding the performance of a self-test, (ii) the actual performance of the self-test, (iii) the interpretation of the test result and (iv) the consumer's follow-up behaviour based on the test result.⁴ In addition to true home tests, three additional types of self-tests are available, namely (i) street corner tests that are offered by organizations and are administered in public places such as supermarkets, (ii) direct-access laboratory tests for which consumers can visit a laboratory and (iii) home collect tests for which body material is sent to a laboratory.

Although self-testing is a relatively new area and is still in a state of flux, it is a phenomenon that cannot be ignored. In 2008, 18.1% of a sample of Dutch Internet users had ever used a self-test and 18.3% probably or definitely intended to use a self-test in the future, whereas the corresponding figures for 2006 were 16 and 17%, respectively (Grispen JEJ, Ickenroth MHP, Ronda G, Hurenkamp L, De Vries NK, Van der Weijden T, Submitted).^{2,5} However, the value of self-tests has been questioned; it is unclear whether self-tests are used in a way that is advantageous to the users and

the consequences of self-testing are still unknown.⁶⁻⁹

An important prerequisite for proper self-test use is an instruction leaflet that provides good quality information on how to use the self-test. Research regarding patient information leaflets (PILs) indicates that good quality PILs improve a patient's retention of the information and increase the likelihood that the patient will use this information appropriately.¹⁰⁻¹² Despite European legislations to improve the quality of PILs (e.g. <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/1171&format=HTML&aged=0&language=EN&guiLanguage=en>), studies have shown that the overall quality of PILs is insufficient, for instance in that scientific medical terms are frequently used, clear instructions are lacking and the use of long paragraphs make the texts hard to understand.^{10,12-14} Given these findings and the lack of knowledge about the quality of the information provided with home test kits, combined with the fact that self-tests are easily available and widely used,^{2-4,5} it is important to know if the instructions accompanying self-tests are of good quality and whether they fit in with the actual use of information by consumers and their needs concerning self-test information. The purpose of the present study was therefore to assess whether the instruction leaflets that are included in diagnostic self-test kits for home use satisfy the consumers' information needs regarding self-testing and whether this information complies with medical guidelines. This was assessed by means of two independent studies. In the first study, we used an online Internet panel to identify (i) the way consumers use the information and their information needs concerning self-testing and (ii) the perceived quality of the consumer information provided with home test kits. In the second study, we assessed the quality of consumer information accompanying home test kits by reviewing information leaflets using a checklist of quality criteria. As these were two independent studies, the information leaflets used in the first study could not be matched to those used in the second study.

Study 1

Methods

Participants and procedure

A cross-sectional survey was performed by Flycatcher, a Dutch ISO-certified institute for online research, which took care of the recruitment of participants and the distribution of the questionnaires. The Flycatcher panel currently consists of approximately 14 000 active members between 12 and 96 years old. Members of the panel are recruited online, by written invitation, face-to-face contacts or by intermediaries. Individuals aged 12 years or older who have an e-mail address can apply to join the Flycatcher Internet panel by registering at the Flycatcher website (www.flycatcher.eu). Compared with the Dutch population, the panellists are overall younger, have a higher level of education, and are more often female. The total panel is representative of the Dutch Internet population. Panel members receive invitations to participate in online questionnaires approximately eight times per year and receive an incentive when they have completed a certain number of questionnaires. Socio-demographic characteristics of the panellists for example, age, gender and level of education, are provided by Flycatcher.

For the current study, a total of 6700 panellists were approached by e-mail to participate in this study. The e-mail provided a link to the questionnaire. After 1 week, a reminder was sent, including an expiration date after one additional week for participation. Panellists received a gift voucher after completion of the questionnaires. For the current study, we only selected panellists who indicated having used a home test as these are tests in which consumers are responsible themselves for performing the test and interpreting its result, and for their follow-up behaviour, and it is therefore very important that consumers understand and are able to use the tests by themselves.

Ethical approval

The Medical Ethical Committee of Maastricht University Medical Centre indicated that no ethical approval was needed for this study.

Measurements

This survey used two consecutive questionnaires.⁴ The first determined the prevalence of the use of self-tests and the intention to use self-tests, the types of self-tests used and a number of lifestyle characteristics of the respondents (e.g. perceived health status).

After 2 months, a second questionnaire was sent to all respondents who had reported having used a self-test. Respondents received a questionnaire concerning the test they had used (e.g. cholesterol test), assessing their use of the information and their information needs as well as the perceived quality of the consumer information provided with the test kit package. Tables 2 and 3 provide an overview of the answering options for information use and information needs.

Information use. The way the information was used was assessed by nine items, for example, 'Before you tested yourself (or had yourself tested), had you heard or read any information about this test?' If respondents indicated to not have heard or read information concerning the self-test, no additional questions concerning the information were asked.

Information needs. Information needs were assessed by two items, 'In what way would you prefer to get information about self-tests?', and 'What would be important for you to know before you do a test?'

Perceived quality of the consumer information.

The respondents' perception of the quality of consumer information was established by assessing six different aspects associated with quality, asking 'What was your general opinion about the information you heard or read?', with answering options 1 = very poor – 5 = very good; 1 = very hard to understand – 5 = very easy to understand; 1 = very unclear – 5 = very clear; 1 = very unreliable – 5 = very reliable; 1 = very incomplete – 5 = very complete; and 1 = very difficult – 5 = very easy. These quality aspects were assessed for all four self-test phases and were combined into four overall quality

measures within each test phase; ‘before testing’ (Cronbach’s α 0.92), ‘information on the actual use of the test provided on the package’ (Cronbach’s α 0.96), ‘information on the actual use of the test provided in the instruction leaflet’ (Cronbach’s α 0.97), and ‘information on the interpretation of the test result’ (Cronbach’s α 0.95). These overall quality scores for each test phase were combined into one overall quality score (Cronbach’s α 0.93).

The complete questionnaires that were used in this study are available elsewhere.⁴

Statistical analysis

Analyses were performed using spss 17.0. Basic descriptive statistics were used to describe the respondents’ socio-demographic and lifestyle characteristics, their information use and information needs and the perceived quality of the consumer information.

Results

Socio-demographic characteristics

The first questionnaire was sent to a total of 6700 panellists and had a response rate of 66%. The second questionnaire was sent to all respondents who had indicated in the first questionnaire to have performed a self-test ($N = 703$, response rate 79%). Participants who indicated having used an ovulation test or a test in the ‘other’ cate-

gory were excluded as ovulation tests are often performed by healthy individuals and information on the tests used in the ‘other’ category was lacking. For the current study, we only selected individuals who had used a home test resulting in a total of 305 respondents who were selected for further analyses (Fig. 1). Of the 305 respondents who had ever used a home test, 112 indicated to have a chronic condition or a disability, varying from psychological problems (e.g. ADHD, bipolar disorders), chronic pain (e.g. migraine, chronic back pain), pulmonary disorders (e.g. COPD) and diabetes to high blood pressure. Respondents were between 18 and 77 years of age, with a mean age of 41.8 years ($SD = 13.02$). Table 1 describes the socio-demographic characteristics of the self-testers.

Information use

A large majority of the respondents indicated having read the consumer information accompanying the test before testing (i.e. before deciding to buy or use the self-test), as well as when performing the test, and while interpreting the test result. Most respondents indicated that this information had helped them to better use the self-test. The most frequently read information concerned the use of the test, the target population of the test, what disease or risk factor the test identifies, the meaning of the test result and the reliability of the test result. See Table 2.

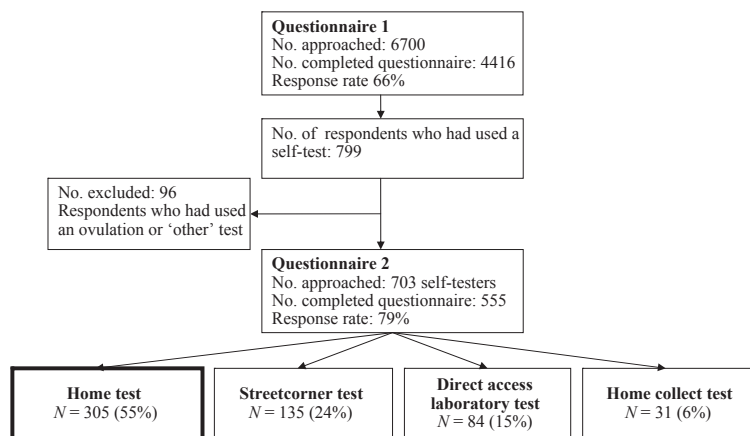


Figure 1 Flowchart for the questionnaires.

Table 1 Characteristics of self-testers

Characteristics N = 305	Respondents N (%)	Dutch population ¹ %
Age (mean and SD in years)	M = 41.80 (SD = 13.02)	M = 40.3
Gender		
Male	87 (28.5%)	49.5%
Female	218 (71.5%)	50.5%
Level of education ²		
Low	58 (19.0%)	31%
Intermediate	133 (43.6%)	41%
High	114 (37.4%)	28%
Test		
Kidney disease	121 (39.7%)	
Diabetes	70 (23.0%)	
Urinary tract infection	36 (11.8%)	
Cholesterol	26 (8.5%)	
Female fertility	13 (4.3%)	
Allergies	8 (2.6%)	
Chlamydia	7 (2.3%)	
Glandular fever	6 (2.0%)	
Aids/HIV	5 (1.6%)	
Other	13 (4.4%)	

¹Numbers provided by Statistics Netherlands (www.cbs.nl).

²Low = primary and secondary school, Intermediate = intermediate vocational education, high = higher vocational education and university.

Information needs

Respondents indicated that they preferred the Internet, a pharmacy, their family doctor or specialist, or brochures at their family doctor's office as sources of information about self-testing.

The information topics considered to be the most important to know before doing the test were instructions for carrying out the test, the reliability of the test result, the disease or risk factor identified by the test and the meaning of the test result. Table 3 provides an overview of all information needs.

Reported quality of consumer information

The mean quality of the instruction leaflets on information before testing was 3.98 (SD = 0.63), on information on the actual use of the test provided at the package was 3.91 (SD = 0.69), on information on the actual use of the test provided in the instruction leaflet was 4.02 (SD = 0.68), and on information on

Table 2 Information use

Test phase item answering options/N = 305	N (%)
Before testing (before deciding to do the self-test)	
Before you tested yourself (or had yourself tested), had you heard or read any information about this test?	
Yes	254 (83.3)
No	51 (16.7)
What was the information about? (multiple answers allowed)	
How the test should be carried out	167 (54.8)
For whom the test is intended	133 (43.6)
What disease or risk factor the test identifies	129 (42.3)
The meaning of the test result	121 (39.7)
The reliability of the test result	97 (31.8)
Where the test is done or sold	50 (16.4)
The costs of the test, and if they are reimbursed by my insurance	34 (11.1)
Whether I can have the test done at my family doctor's	11 (3.6)
Other, namely.....	9 (3.0)
Actual performance of the test	
Did you read the information on the packaging before you bought the test?	
Yes	241 (79.0)
No	34 (11.1)
Not applicable, there was no information on the packaging	30 (9.8)
Do you think the information on the packaging helped you to better perform the test?	
Yes	240 (78.7)
No	23 (7.5)
Missing	42 (13.8)
Did you read the information in the instruction leaflet about the way to perform this self-test?	
Yes	272 (89.2)
No	14 (4.6)
Not applicable, the instruction leaflet was not included	19 (6.2)
In your opinion, did the information in the instruction leaflet help you to better perform the test?	
Yes	248 (81.3)
No	24 (7.9)
Missing	33 (10.8)
Interpretation of the test result	
Did you read the information about the meaning of your test result in the instruction leaflet?	
Yes	269 (88.2)
No	17 (5.6)
Not applicable, this information was not included in the instruction leaflet or the instruction leaflet was missing	19 (6.2)
Do you think this information helped you to better interpret your test result?	

Table 2 Continued

Test phase item answering options/ <i>N</i> = 305	<i>N</i> (%)
Yes	241 (79.0)
No	28 (9.2)
Missing	36 (11.8)

Table 3 Information needs

Item answering options/ <i>N</i> = 305	<i>N</i> (%)
In what way would you prefer to get information about self-tests? (multiple answers allowed)	
From the Internet	151 (49.5)
At the pharmacy	137 (44.9)
From my family doctor, from a specialist	122 (40.0)
At my family doctor's office (e.g. from a brochure)	116 (38.0)
E-mail	82 (26.9)
At the chemist's	58 (19.0)
From TV or radio	58 (19.0)
From newspapers, magazines or books	58 (19.0)
From relatives, friends or colleagues	40 (13.1)
At the supermarket	13 (4.3)
Text message	2 (0.7)
Other, namely.....	3 (1.0)
What would be important for you to know before you do a test? (multiple answers allowed)	
How the test should be carried out	242 (79.3)
The reliability of the test result	225 (73.8)
What disease or risk factor the test identifies	205 (67.2)
The meaning of the test result	201 (65.9)
For whom the test is intended	169 (55.4)
The costs of the test, and if they are reimbursed by my insurance	142 (46.6)
Where the test is done or sold	88 (28.9)
Whether I can have the test done at my family doctor's	49 (16.1)
Other, namely.....	2 (0.7)

the interpretation of the test result was 3.93 (SD = 0.72). The overall mean quality score of the information was 3.94 (SD = 0.61).

Study 2

Methods

Identification of instruction leaflets

An Internet search was used to identify instruction leaflets for home diagnostic tests that are available online, as most home self-tests avail-

able in the Netherlands can only be purchased online instead of being available at drugstores or pharmacies. To identify these leaflets, we used the meta-search engine Google as most consumers indicated in previous research to start an Internet search using Google (Grispen JEJ, Ickenroth MH, Hurenkamp L, Ronda G, De Vries NK, Van der Weijden T, Submitted). In an iterative search process, we searched for (i) each of the following key words in English and in Dutch: self-testing [zelftesten], self-test [zelftest], self-test [zelf test], home test [thuis-test], point-of-care test, and (ii) each test by name and (iii) by manufacturer. Instruction leaflets were excluded if they were not available in Dutch or English, if they concerned test methods other than *in vitro* home diagnostic tests or if they were not available online. The selected set of self-tests consisted of all instruction leaflets included in home test kits that were available online at the time of the study and included instruction leaflets for tests on Candida, Chlamydia, syphilis, urinary tract infections, cholesterol and diabetes. If different producers marketed the same test or if different tests were marketed for the same purpose, all available types were included. Of the websites found by Google, the first 70 hits for each key word were consulted. Our method was based on the methods used by others in which the first 20 hits were assessed.¹⁵ As we found new additional information after viewing the first 20 hits, we decided to assess additional hits until data saturation was met. After reviewing the first 50 hits, we saw that the following hits were not directly related to our search criteria, and after 70 hits data saturation was met as no relevant sites were found additionally. If one of the initial web pages contained a relevant link to another web page that page was also examined. The available consumer information was then downloaded from the Internet. The search was performed in July 2009 and updated in July 2010.

Assessment of information quality

Specific guidelines for assessing the quality of consumer information accompanying self-tests

were not available at the start of our study. However, the European *In-Vitro* Diagnostic guidelines describe the essential requirements which *in vitro* diagnostics have to meet.^{16,17} Furthermore, the International Patient Decision Aids Standard (IPDAS),^{18,19} Discern,^{20,21} a checklist to assess manufacturers' documentation on medical diagnostic self-tests,²² and a checklist to assess the quality of websites marketing medical home diagnostic tests were available.¹⁵ These information sources were combined with information derived from previous research to generate a checklist for assessing instruction leaflets on self-testing (Grispén JEJ, Ickenroth MHP, Ronda G, Hurenkamp L, De Vries NK, Van der Weijden T, Submitted).^{2,5,23,24} Consensus was achieved among the research team on the items that were included in the checklist. Our research team consisted of experts in the field of health promotion, medicine, cognitive psychology, epidemiology and clinical practice guidelines. The complete checklist is presented in Table 4.

Data extraction and analysis

The checklist for assessing the quality of instruction leaflets on self-testing consisted of 25 items, each reflecting a specific quality criterion which was considered an essential feature of good quality consumer information. The items were subdivided into three groups: (A) *product description* – seven items regarding the features of the product under evaluation; (B) *content* – 16 items regarding the content of the instruction leaflet on the practical use of the self-test; and (C) *information source* – two items about the origin of the instruction leaflet. Items were assessed using a dichotomous scale with answering options 0 = *the information is not included*, and 1 = *the information is included*. All instruction leaflets were reviewed by two researchers (JG and MI), and any disagreements were resolved in consensus meetings. See Table 4.

Results

A total of 21 instruction leaflets were analysed, 11 of which were in Dutch and 10 in English.

We selected instruction leaflets included in test kits that tested for one of seven different diseases or conditions, namely Chlamydia ($n = 2$), urinary tract infections ($n = 2$), syphilis ($n = 2$), diabetes ($n = 3$), Candida ($n = 3$), total cholesterol ($n = 5$) and cholesterol ratio ($n = 4$). The number of quality criteria that were met ranged from 6 to 23 for a total of 25 proposed quality items, with a mean score of 17.1 (SD = 3.8).

Compliance with quality criteria

Section A

All instruction leaflets provided pictures as well as text to clarify the self-testing procedure. Approximately 80% of the instruction leaflets provided a date at which the information had last been updated. Only one instruction leaflet provided scientific references for the claims about the reliability of the test (Table 4).

Section B

All leaflets provided information on how the test should be used, including the interpretation of the test result. Information on alternative test options was lacking from all leaflets. Almost all leaflets listed the content of the test kit (81%) and provided information on the expiration date of the test (86%), the health condition the test was designed to detect (90%), what the test measured (95%), when to use the test (86%), how to contact the service department of the test manufacturer (81%) and how to store the test (90%). The vast majority of the leaflets (95%) provided information on what to do in case of a positive result. However, one-third of the leaflets did not provide information on the actions that should be taken when a negative or inconclusive test result was obtained (33 and 43%).

Approximately half of the leaflets described the likelihood of obtaining correct positive or correct negative results, whereas 86% described the likelihood of getting a false-positive or a false-negative result. Information on the target group was only provided in 52% of the leaflets and was more often reported in English leaflets than in Dutch leaflets (70 and 36%). Only

Table 4 Checklist to assess the quality of consumer information leaflets accompanying diagnostic self-tests

Quality criteria	Yes N (%)	No N (%)	% Of initial agreement
Section A. Product description			
Visuals	–	–	
Pictures	21 (100)	–	100
Diagrams/tables	8 (38)	13 (62)	100
Instruction video	3 (14)	18 (86)	100
FAQ-section present	12 (57)	9 (43)	100
When was the information last updated?	17 (81)	4 (19)	100
Are research references presented?	1 (5)	20 (95)	100
Does the producer guarantee the product's quality?	7 (33)	14 (67)	100
Section B. Content			
Lists the contents of the test package	17 (81)	4 (19)	100
Specifies use-by date	18 (86)	3 (14)	100
Indicates whether test was correctly performed	14 (67)	7 (23)	100
Describes the relevant health problem	19 (90)	2 (10)	81.0
Describes what the test determines	20 (95)	1 (5)	90.5
Identifies the target group of the test	11 (52)	10 (48)	85.7
Indicates other test options/alternative tests	–	21 (100)	81
Describes how the test is to be carried out			
Provides instructions for using the test (including interpretation of the test result)	21 (100)	–	100
Indicates when the test is to be used	18 (86)	3 (14)	90.5
Describes the likelihood of:			
Correct test results	11 (52)	10 (48)	85.7
False-positive or false-negative test results	18 (86)	3 (14)	85.7
Describes possible further actions in case of:			
A positive test result	20 (95)	1 (5)	95.2
A negative test result	14 (67)	7 (33)	66.7
An unclear test result or test failure	12 (57)	9 (43)	90.5
Other			
Indicates where users can ask questions	17 (81)	4 (19)	95.2
Provides information on storage conditions	19 (90)	2 (10)	95.2
Section C. Information source			
Describes what organisation is responsible for the development and distribution of the test	20 (95)	1 (5)	90.5
Presents disclaimer in the consumer information	19 (90)	2 (10)	57.1

46% of Dutch leaflets included a FAQ-section as compared to 70% of the English leaflets. Half of the English tests provided an indication if the test had been performed correctly, whereas 82% of the Dutch tests provided this indication (Table 4).

Section C

Almost all instruction leaflets provided at least the name of the manufacturer of the self-test (95%) and included a disclaimer excluding responsibility for any consequences related to the use of the self-test (90%; Table 4).

Discussion

To the best of our knowledge, no research to date has examined the use of and needs for information among self-testers or the consumers' perceived quality of information accompanying home test kits, while independently assessing the quality of consumer information using a checklist of quality criteria. This study was a first attempt to gain more insight into these factors and to provide directions for future research. The information needs that were reported by consumers who had used a

self-test were in line with the topics that were most frequently read in the instruction leaflets, namely instructions for performing the test, the reliability of the test result, the disease or risk factor identified by the test and the meaning of the test result. According to the respondents, the information in the instruction leaflets was of moderate to good quality, and they reported that the information had been helpful in using the self-test correctly.

Our quality assessment of consumer information by means of the checklist showed that the instructions for carrying out the test, the disease or risk factor assessed by the test, and the meaning of the test result were provided in most information leaflets. Although some information on the reliability of the test result was presented, it was very limited. Whereas 86% of the leaflets indicated the likelihood of obtaining incorrect test results, only 52% of the leaflets mentioned the likelihood of correct results. It must be noted that we merely assessed whether a particular aspect mentioned in the criterion was present in the leaflet, but did not evaluate its completeness or quality. Most information on false-positive or false-negative results was very limited and only consisted of a brief statement such as 'false-positive or false-negative results may occur'.

These results are unfortunately not surprising. The essential requirements described in the European *In-Vitro* Diagnostic guidelines relate to the analytical, diagnostic and clinical validity of self-tests.^{16,17} Manufacturers of low-risk self-tests are allowed to determine for themselves whether their product meets these essential requirements of the IVD guidelines and are allowed to provide their product with a CE (Conformité Européenne) mark as a stamp of quality. This leads to claims of extraordinary test performances that are based on comparisons between the self-test and an unknown reference test. The CE mark does not provide information on the diagnostic value of the test and conceals the likelihood of false-positive and false-negative test results.^{16,25}

Information on the interpretation of the test result was provided in all information leaflets.

However, since they offered no indication of the likelihood of false-positive and false-negative test results was offered, consumers are unable to correctly interpret their test result. Where information on the reliability of the test result was provided, it was phrased as 'laboratory tests have indicated that this test is reliable in 99% of the cases'. These so-called reliability claims provide very limited information on the diagnostic value of the test.¹⁶

The results of our quality assessment by means of a checklist demonstrated that information on alternative test options was lacking from all leaflets and information on the target group of the self-test was given in only 52% of the leaflets. This information is one of the things that are essential for consumers to make an informed decision about using a self-test.

Study limitations and strengths

The Flycatcher Internet panel enabled us to reach a large sample of Dutch Internet users. This panel of Internet users differs in some respects from the general Dutch population in that panellists are slightly younger, more often female and more highly educated.² However, as self-tests are often bought via the Internet, we consider the use of this Internet panel as an acceptable option.

The current study was conducted to gain more insight into the use of and needs for information among self-testers as well as into the quality of the consumer information accompanying home test kits. We assessed these factors by means of two independent studies, and we were therefore not able to match the information leaflets that were used by the consumers to the information leaflets that were assessed by using the checklist. However, there are two main manufacturers of self-tests in the Netherlands and we might assume that most home self-tests that were used, were produced by those manufacturers. The leaflets of the home tests under investigation were mainly from those two producers. Therefore, we might assume that there is a significant overlap between the leaflets under investigation and the home tests used by our participants.

The process of developing our checklist to assess the quality of the consumer information accompanying self-tests could have been optimized by using a large-scale Delphi study but financial and logistic limitations meant we had to restrict ourselves to a small Delphi study among the experts of our research team. Additionally, the quality criteria and the coding method, we used directly influenced the validity of our findings. We coded whether the aspect mentioned in the quality criterion was present in the leaflet but did not evaluate it for completeness or sufficiency. We decided not to prioritize quality aspects, in view of the lack of an empirical basis for prioritization. In the absence of specific quality guidelines for information leaflets included in home test kits, we based our checklist on results of previous research (Grispén JEJ, Ickenroth MHP, Ronda G, Hurenkamp L, De Vries NK, Van der Weijden T, Submitted),^{2,5,23,24} the IPDAS criteria for decision aids,^{18,19} the Discern criteria for judging the quality of written consumer information on treatment choices^{20,21} and the Dutch regulations for content of IVD patient information.^{16,17} We consider our checklist to have sufficient face validity, to be evidence-based and to be well founded in theory and therefore conclude that our observations on the quality of information leaflets included in home test kits appear valid.

Practical implications and future research

Although the advantages and disadvantages of self-testing are currently not clear, self-testing is an existing phenomenon that is likely to become more popular in the future. It is therefore essential that appropriate consumer information is developed, to provide a solid basis for informed choices about self-testing. The current study was a first attempt to assess the actual quality of the information leaflets included in self-test kits by means of a checklist of quality criteria. However, as we chose to code only whether the aspect mentioned in a criterion was indeed present in the information leaflets or not, our quality assessment was limited. Our checklist should be extended with

specific quality criteria scored on, for instance, a 5-point Likert scale, accompanied by a detailed description, to obtain a more complete picture of the quality of information leaflets.

In the present study, information needs were identified after the consumers had used a self-test. This may have resulted in a biased view of the information needs, as these could have been influenced by the actual use of the consumer information when performing the self-test. Future research should be aimed at determining the consumers' information needs before they use a self-test and to identify the consumers' actual use of the information after they have performed a self-test, to determine whether consumers' information needs and their use of information correspond.

Additionally, besides identifying consumers' information needs and use, it is important to simultaneously assess the level of health literacy of the average self-test user. The effectiveness of an information leaflet does not only depend on the quality of the information but also on the level of skills people have to understand and use the information that is provided. Therefore, we have to determine whether the information leaflet corresponds to the level of health literacy of its users.²⁶

Furthermore, to gain more insight into the implications of self-test use in the medical practice, it is important to investigate the opinion of GPs towards self-testing and to identify how often they are confronted with patients who made an appointment based on their self-test result and, in line with this, to identify how GPs respond to these patients. Therefore, future research should be aimed at identifying the GPs' opinions on self-testing and their experiences with patients who used a self-test by means of semi-structured interviews.

In view of the biased and optimistic presentation of data on reliability, validity and diagnostic value to potential consumers, European legislation concerning quality criteria for self-tests and the accompanying consumer information needs to be extended and enforced more strictly. Self-test producers need to be monitored by an independent external committee to

check whether the claims made by the self-test kits are truthful and are not manipulated to disguise unfavourable properties. Only if the legislation on self-tests and the accompanying information leaflets is adapted and producers are forced to comply with these legislations, will consumers be able to make an informed decision on the use of a self-test.

Conclusions

Overall, instruction leaflets were of reasonable quality and met most medical guidelines. However, we only scored whether certain required information aspects were present, but not whether this information was sufficient or complete. A closer inspection of some criteria showed that information on certain aspects, such as reliability was insufficient. European legislation on self-tests needs to be adapted and enforced more strictly in order to provide consumers with a complete overview of the properties of self-tests. A complete overview of all available information about self-tests may enable consumers to make informed decisions about using or not using a particular test.

Acknowledgement

This study was funded by the Netherlands Organisation for Health Research and Development, grant number 50-50101-96-406. Supplementary financial support has been provided by the Central Ziekenfonds (CZ) health insurance company. None of the sources of funding influenced the study design, the writing of the manuscript or the decision to submit the manuscript for publication.

Conflict of interest

The authors declare that they have no competing interests.

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