National Consultative Ethics Committee for Health and Life Sciences

Opinion n° 86

Problems connected to marketing self-test kits for HIV screening and diagnosis of genetic disease

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In January , 2004, the *Directeur Général de la Santé* (Director General Health Services) referred to CCNE requesting an opinion on ethical problems raised by the sale in France of self-testing kits to screen for HIV contamination and to diagnose genetic diseases.

These are not the first self-test kits to be made available following the development of new medical technology. Other quick testing devices already exist for various purposes (pregnancy, glycaemia, streptococcal throat infections, reagent strips for urinalysis). However, the above are limited in their purpose to identifying a status (for example self-measurement of blood pressure) or for monitoring treatment, whereas in this case the object is very different in that it concerns diagnosis of potentially serious diseases and not simple monitoring.

1 – Description and inventory

Following a European directive in 1998, self-test kits only need EC labelling to be licensed for sale. No information or registration procedure with AFSSAPS (French health products safety agency) is needed and this agency is aware of the market players but not of the products sold. It would seem however that for the moment the products mentioned in the referral are not sold on the French market. However, there may well be rapid developments in this respect, in particular for diagnosing HIV contamination for which a great number of commercial offers – mostly from the United States and in some cases authorised by the FDA, but also from certain European countries – are to be found through Internet.

There are two separate kinds of self-tests: home self-sampling and home self-testing. In the first case, the person concerned takes on the sampling procedure. Generally, a small sample of blood is deposited on absorbent material which is then coded and sent to a laboratory for analysis. More recently, a system requiring no more than a saliva sample for HIV (or a buccal scraping for a DNA test) was put on the market in the United Sates. The person concerned then telephones the laboratory to get test results and the coding system preserves anonymity. If the test results are positive, the person concerned is usually connected to someone who can give explanation and advice over the telephone. The second kind of test raises some serious problems because the entire procedure – sampling, reading and interpreting results with all the potential risk of error – is done at home by the person concerned,

People are therefore left on their own to cope with test results without any possible help from healthcarers.

Self-test kits use various techniques depending on whether they are screening for infectious, metabolic or genetic disease. Clear information on how they should be used, possible interpretation problems, and clinical significance and its limitations should always be appended.

Technical problems related to quality, reliability and validity of the self-tests should not be neglected. Of course, technology never ceases to improve so that the gap in quality between self-tests and laboratory tests will gradually diminish. Evidence of a prerequisite of technical acceptability is not sufficient to minimise ethical issues.

2 – Self-testing and the right to know

The possibility of acquiring information about oneself so that decisions on health options are based on access to a source of pertinent data is part on an individual's right to information and self-determination, as stated generally by the European Convention on Human Rights. On the more specific question of information about health, the French law on patient rights dated March 4th 2002 laid emphasis on this concept. However, the present trend for more and more knowledge, which carries the risk of creating the illusion that a subject is totally mastered, must not compromise the quality of that knowledge. The right to know must be exercised with due respect for the necessary protection of individuals, in particular those who are vulnerable. The issue of self-testing must therefore be viewed in the general context of regulating this freedom of access, or even restricting it, should there be any risk of harmful effects for the person concerned or for others, in particular discrimination.

There are a certain number of issues which are cause for some concern:

- Should some official body refuse the very principle of self-testing, for whatever reason, it could be accused of challenging a legitimate right to know and hindering to some extent freedom of access to personal data.
- Should it accept the principle but fail to provide for reimbursement by the national health system, it could be accused of being a deliberate source of financial discrimination and thereby disrupting social solidarity.
- Self-testing could also raise the issue of its relationship to medicine in general. The medical profession has always considered that requests for additional testing should be based on medical considerations and that patients are not always in a position to judge what is needed. Self-testing, which represents a legitimate desire to increase patient autonomy, would therefore be a new departure in medical practice which merits consideration. Can the medical world keep in its possession all the keys to information that people want to have about themselves at a time when a justified tendency to share "power" between patients and their doctors is emerging? Is it right, to the extent that it is possible, to consider levelling the relationship's imbalance?
- Making self-test kits available to people provides them with the possibility of acquiring information without the help of professionals or before seeking their advice. Is this simply a change in the timing and context of a test which is only the first phase of a global treatment process or is it an encouragement to replace an interactive counselling process by a solitary test, which is disconnected from the global healthcare procedure? So far, emphasis has always been on interactivity, part of which is represented by free and informed consent. In fact, self-testing provides more freedom and less enlightenment in its normally acceptable medical form and raises the general question of access, outside the healthcare system, to partial information which frequently involves serious consequences for users and sometimes for their close relatives. Self-tests only make sense if they are part of coherent multidisciplinary management of a medical condition. The problems that arise are not limited to pertinence or legitimacy of use. There is also a real public health issue in which autonomy of decision takes centre stage. Some people consider that if the information available by these tests is exact and comprehensible, there is no reason to

prohibit them. If that is so, the issue would be more concerned with the quality of information and whether it is comprehensible than with prohibition.[1]

3 – The objectives of self-test kits

Specifically, the questions raised by the referral bear on screening for HIV contamination and for genetic diseases as part of predictive medical practice (already mentioned in CCNE's Opinion n° 46)[2]. These two varieties of self-test kits are in fact very different even though they have points of similarity. Beyond the issue of simply obtaining results, the question of their interpretation remains essential. HIV contamination does of course involve relationships with others since the infection could be transmitted, but it does not entail, contrary to certain genetic diagnosis tests, the same general responsibility of providing information to, for example, the subject's family (mentioned in Opinion n° 76). A genetic disease or rather, an identification of genetic status, as we shall see below, is a permanent situation which could be of immediate concern to the whole family in the case of certain diseases. The confusion between disease and "status" can be particularly potent in such cases. Although information regarding HIV contamination is simply limited to the presence or absence of seropositivity, genetic information generally implies an advanced degree of complex interpretation.

Screening for HIV contamination

HIV contamination still occupies very distinctive ground because of repeated anxiety after risk-taking and persisting social ostracism. It is therefore entirely possible to accept that those concerned may prefer to find out whether they are or are not contaminated in an entirely confidential setting without needing to undergo the scrutiny of society.

Such screening by public or private licensed laboratories involves antibody research procedures as a first step by a relatively simple method. The name of the procedure is Elisa and two different reagents are used. If one or the other of the reagents provides evidence of a positive our doubtful reaction, research can continue with a less simple procedure (Western Blot) which is the only means of arriving at a positive or negative conclusion. In the case of recent contamination (under a month), in order to avoid a falsely reassuring interpretation it is essential to emphasise that the results of the tests will be **negative**, although the person concerned is in fact contaminated. In order to limit the risks connected to this one month "window" (which corresponds to an early stage during which the person already contaminated by the virus has not yet developed the antibodies which enable a diagnosis to be made) more recent testing procedures add a simultaneous search for a viral antigen which appears earlier after contamination.

The fast tests which are sometimes part of a medical procedure and which could be marketed as self-test kits are probably less reliable than the Elisa tests used in laboratories. They generally prefer sensitivity to specificity which is the reason for false positive results. The high frequency of these falsely positive test results within populations where HIV contamination has a relatively low prevalence has been underlined in an Opinion published in 2002 by the Belgian Consultative Ethics

[1] Ref. Ludvig Beckman "Are genetic self-tests dangerous ? Assessing the commercialization of genetic testing in terms of personal autonomy", Theoretical medicine and bioethics, 2004, Vol. 25, n° 5/6, pp. 387-398

[2] Opinion n° 46 "Genetics and medicine : from prediction to prevention". October 30, 1995.

Committee[3] which provides a remarkable analysis of points in favour or against self-testing. Confirmation by the Western Blot technique is an absolute necessity. Furthermore, some of these rapid test procedures do not distinguish between HIV1 and HIV2 which contaminates certain populations in some African countries.

Being able to perform self-screening for HIV contamination with the help of self-test kits can however, be useful on several counts.

It could help to provide earlier diagnosis so that a greater number of people become aware of their serum status, but this argument is probably faulty because a fairly large proportion of patients who come to hospital with full-blown AIDS do not know that they are HIV positive and had previously rejected screening.
It could theoretically protect confidentiality and avoid stigmatisation altogether. It could allow a more responsible attitude to sexual activity. It could save patients from having to face up to involvement with healthcare structures. It should be mentioned with regret in this context that anonymous and free screening centres are still very rare outside the French capital.

The lack of supervision and counsel by a professional healthcarer before undergoing the test is a reason to underline the importance of the negative window. Since contamination is not revealed by the test, the window can lead, paradoxically, to an increase in risk-taking behaviour as a result of a negative self-test. It is known that in the negative period before seroconversion carriers are probably at their most contagious. Speaking to a professional healthcarer is therefore essential when screening is performed and results are revealed. The possibility of a speaking on the telephone to a competent person when a positive result is announced after self-sampling at home is widely considered to be insufficient and unsatisfactory. With home self-testing, users confronted with an apparently positive result are isolated, sometimes in the throes of deep emotional reactions, although a false positive is a distinct possibility. The absence of medical management is a complete denial of medical responsibility and opposed to public health policy. The administrative and social management, which should accompany the announcement of a positive result, is not provided, in particular as regards people in precarious circumstances (who would anyway hesitate to use a test which is not reimbursed by the national health system). Trivialising the test could lead people to underestimate the importance of submitting to screening for such a serious disease. The problem would be minimised and, as mentioned previously, risk-taking behaviour would paradoxically be encouraged.

Nor should the possible risk of abuse be neglected, for example pressure or coercion by a partner, a family, an employer, an insurer or the police. The techniques in discussion, which are theoretically a way of avoiding problems related to consent, could in fact sometimes jeopardize principles of respect of individual rights.

Since at present in this country HIV-positive status, and not the disease itself, triggers mandatory (albeit anonymous) reporting, self-test screening causes the loss of important epidemiological data.

Finally it must be recognised that sampling, reading and interpreting results are procedures which offer ample opportunity for mishap, faulty handling and defective

[3] Opinion 17 dated June 10th, 2002, on the ethical aspects of self-test kits for HIV screening, Bioethica Belgica, 2004, n° 13

manoeuvres when they are carried out by the person concerned and, according to a recent study by the Centers for Disease Control (C.D.C.) in Atlanta, this does appear to be particularly frequent.

Altogether these drawbacks, many of which are of an ethical nature, would seem to outweigh the advantages of marketing self-test kits, even if potential users are assumed to be responsible people.

CCNE considers that users should be given due warning and that use of these kits should be restricted, although CCNE is well aware that in practical terms, restricting use is difficult[4].

Although marketing and reimbursement of a rapid test method could possibly be encouraged on the premises of patient support groups, family planning centres, drug abusers' support groups, in school and university sickrooms, in work places, or in private doctors' surgeries (including the counselling previously mentioned), selling HIV self-test kits in pharmacies should be discouraged. But if they were, as a minimum a very carefully worded booklet should be included in the transaction, underlining the difficulty of interpreting test results, its limited significance and a warning against its use without confirmation from an approved laboratory and the assistance of a healthcaring institution (with a list of useful addresses). Since the kits have no claim to national solidarity, they should not be reimbursed by the social security system.

Amply illustrated by a number of existing websites, leading to wasteful consumption, exploitation of anxiety for lucrative purposes and fools' bargains to the detriment of financial resources available for collective healthcare, aggressive marketing should be opposed.

Reservations expressed in this Opinion concur with the conclusions of a 1998 report by the Conseil National du Sida (National AIDS Council) replying to a referral from the Directeur Général de la Santé which raised the issue of whether home-testing equipment should be marketed. These conclusions were updated in the attached Opinion, written in December 2004 by CNS at the request of CCNE.

Diagnosis of genetic diseases and identification of genetic status

Diagnosis of genetic diseases identifying a gene or a given set of genes is increasingly in demand and is generally performed as a result of conclusions reached in a global medical framework.

Compared to other medical data, the right to know takes on another meaning when applied to genetics: the aim is to discover a part of what constitutes the innate "biological being", which is not modified during an individual's lifetime and can potentially be passed on to descendents. It therefore means access to information with permanent validity but also extremely ambiguous predictive characteristics.

[4] Increasing volumes of uncontrolled sales of medicines through Internet are also disquieting. Policing these transactions seems out of the question, but at least consumers are aware that they are bypassing the system at their own risk and peril. The self-test kits market could be organised on similar lines.

A second consideration is linked to the history of genetic science. Diagnostic opportunities first emerged for rare, monogenic and highly penetrant diseases (such as cystic fibrosis) which are serious conditions and generally incurable at the time of diagnosis. This monogenic model has influenced the attitude of the public to genetic data generally, whereas a number of genetic facts are of a different nature. The difference between "hereditary disease" and the "genetic component" of a disease is not always very clearly understood. As a result, there is confusion between the evidencing of a predisposition (hypercholesterolaemia, for example), susceptibility (such as the glucose 6 phosphate deshydrogenase deficiency), and a presymptomatic diagnosis (angiomatosis) of an inevitable disease. As regards clinical or familial pertinence, these situations are very dissimilar.

A third element is linked to media simplification and sometimes exaggeration about genetic discoveries, usually expressed as: "gene responsible for… identified". The frequently multifactorial and complex nature of diseases with a genetic component is well known. Associations between a pathology and genetic markers are clearly of assistance to gain more understanding of the way these diseases develop and interaction between genes and environmental factors, but they have only limited clinical application, even for diagnostic purposes.

The capacity to understand and interpret the various categories of genetic data by both healthcarers in general and the public is still fairly limited, hence the dangers inherent in independent use of these test kits. The clarifications required to understand the exact significance of a test and the complex relationship between genotype and phenotype, make the use of self-test kits fairly irrelevant at the present time unless each case is explained individually.

The exact status of genetics in the medical context is as yet incompletely defined so that it is important to be clear about what type of genetic self-tests are involved. Even in the context of diagnosing diseases, the level of information varies considerably. Simplifying, the following categories can be listed:

Genetic tests to diagnose a disease connected to a single gene (however multiple variants of that gene can be involved, regulation factors or modifying genes play a role and both penetrance and clinical forms vary). Many of these diseases are rare and severe; it is in the domain of these monogenic diseases that truly diagnostic, clinically useful and reliable tests exist and the most progress has been made. Be it for children or adults, it is difficult to accept that diagnosis, particularly pre-symptomatic and associated with the absence of available treatment – as in the now classic case of Huntington's disease – could be based on a test unassisted by any kind of medical multidisciplinary management. There is a need for dialogue before and after testing, which hardly seems compatible with self-testing. Moreover, genetic counselling and assistance for patients' families are a primary concern.

Genetic tests to evidence susceptibility or possibilities of protection against a condition or a complication of a disease. These are less useful for diagnostic purposes and when they are used clinically, it is as part of a body of evidence in the presence of a complex disease. Environmental factors also probably play a more prominent role than genetic factors in such conditions (e.g. coronary disease). Other factors, for example immunological ones in type 1 diabetes, need to be associated to genetic data to enhance their predictive value.

Clinical use of these genetic tests to predict or diagnose is more often than not overestimated and unproven. It is also in this context that sound understanding of the notions of risk and probability is more than ever necessary. Self-test kits used in this domain would seem to be a source of false hopes and groundless anxiety, providing access to information, which is of little clinical worth and does not serve to influence usefully a choice of lifestyle. There is the risk of reinforcing notions of genetic determination or, on the contrary, of the absence of risk for certain pathologies, which could lead to more confusion than enlightenment.
For the time being, it is still essentially in research investigating pathological mechanisms or defining therapeutic targets that genetic information of this nature makes a useful contribution.

As a result, we are confronted with the following dilemma:
On the one hand, a genetic test is available but its interpretation is frequently a complex process before a disease can be diagnosed; on the other, the need for genetic counselling involving the whole family. None of this is compatible with a self-test procedure. Legislators provided for the obligation of prior consent for these tests (and also for HIV contamination for that matter) and presumably this was because they were concerned that results could have extremely diverse meanings and sometimes ominous consequences. The argument of urgency is hardly applicable to the genetic context where time is rarely significant. Finally, it is not because physicians specialising in genetics are few in number that the need for professional assistance can be denied. Efforts are now being made to enable non-medical professionals to provide genetic counselling.
As regards genetic tests for diagnosing monogenic diseases, major problems subsist in terms of quality and validity for a certain number of such tests and a European IPTS[5] report in 2003 placed emphasis on this aspect of the problem and the need for further progress. It seems unlikely that an amplification of the self-test market could be compatible with this requirement[6]. The expert group consulted by the European Commission on the ethical, social and legal implications of genetic testing in 2004[7], in which patient support associations and industrialists were represented, did not explicitly broach the question of self-testing in their 25 recommendations. However, these European recommendations make several pertinent points.

They insist on access to genetic testing (recommendation 6) on the basis of qualified prescription (recommendation 7), accompanied by the provision of information (recommendation 9), in conformity with established standards (recommendation 17) (cf Annex 2).

It is to be noted that the experts' group consulted by the European Commission recommended that genetic tests (which are to be integrated into healthcare systems on the basis of clinical pertinence, appropriately controlled in regulatory terms and placed in the context of suitable counselling) are not compatible with the absence of supervision inherent in self-testing.

[5] Institute for prospective technological studies (this institute is part of the European Commission and is situated in Seville). Title of the report: Towards quality assurance and harmonisation of genetic testing services in the EU. Author(s): IBARRETA, D., BOCK, A.K., KLEIN, C., RODRIGUEZ-CEREZO, E. EUR No: EUR 20977 EN. Year: 2003. http://www.jrc.es/home/publications/publication.cfm?pub=1124

[6] Article 18 of the Oviedo Convention prohibits genetic self-testing kits.

[7] http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/recommendations_eng.pdf

It follows that in the present context the use of self-test kits for the diagnosis of genetic diseases and identification of genetic status is unwarranted and potentially harmful.

This reservation on the possibility for individuals to have independent access to their own genetic data may seem excessive and the underlying reasons that justify it at this time should be the subject of review at a later date.

Conclusion

Self-testing for HIV contamination and genetic data ignores three consequences:

- A biological fact is not equivalent to genuine medical information and has significance that exceeds the unprocessed results.
- The simplistic nature of results devoid of individualised counselling procedures may cause distress, the delivery of socially destructive information and irreversible harmful consequences.
- The present demand for free access to information gives rise to irresponsible marketing inducing utopian delusions. Although this demand may appear to have obvious legitimacy, it in fact ignores the extreme complexity of the body of knowledge concerned. There is frequent confusion, for example, between the HIV virus and AIDS (AIDS being only the disease caused by HIV contamination), between the carrier of a heterozygous status, the bearer of an asymptomatic affection, and monogenic disease.

The proposal to market self-test kits corresponds to this call for access to knowledge at all costs and whatever the consequences, which in itself reveals the consumers' vulnerability. The market is very conscious of this and rushes to satisfy demand, never ceasing to promise truth or to deny the complexity of results. The paradoxical result, more often than not, is anxiety rather than serenity. For these reasons, the use of self-test kits should not just be regulated for ethical reasons; it should also inspire reflection on the myth such tests perpetuate.

Thursday, November 4th 2004

ANNEX 1 – Document of the Conseil National du Sida

Memorandum of Opinion on Commercialisation of HIV Self-Tests

Adopted in plenary session on December 9th 2004

In a letter dated 3 May 2004, the National Advisory Committee on Ethics, to which the Director General on Healthcare had referred the issue of possibly "making viral and genetic self-test kits available to the public", sought Conseil National du SIDA's opinion on the HIV-related aspects of the matter, so that a joint stance could be taken on the matter. Already referred to once in 1998, the CNS underscored, in its opinion(1) , the need for medical supervision in all forms of testing for HIV-contamination. Today, HIV-screening kits can be purchased on the Internet. The expression "self-test" refers to a screening kit for use in the home. Such kits can come in one of two forms(2) : either a self-sampling test, in which the person takes his own blood sample using a kit, in order to send it to a laboratory for analysis; or a self-analysis test, in which the self-sampling kit comes along with material that allows the individual to view his result within 20 to 30 minutes. It is the latter "self-test" – the self-analysis test – that the CNS focuses on more specifically in this opinion. Three questions arise when it comes to making such kits available to the public: the reliability of the results provided; the limits of self-analysis; and unethical use of the kits in such a ways as to foster coercive or discriminatory practices.

The Reliability of Self-Analysis Tests

Though self-tests have not yet received the EC label(3) , the results they yield seem increasingly reliable. The latest trials involving self-analysis tests, as carried out by the Centers for Disease Control (CDC) AIDS Division, in March 2004, show that they, under the best circumstances, they prove 99.8% sensitive and specific, provided that the test is perfectly conducted(4) and that the interval required for antibodies to appear(5) , known as the "sero-conversion window" is taken into account. Such results remain inadequate, however, to fully inform individuals, especially in countries where prevalence is low(6) . With a test posting specificity(7) and sensitivity(8) levels of 99.8%, taking an adult population where the infection's prevalence is around 2 per 1 000, the percentage of false-positives would be around 50%. In other words, seeing a positive result, one out of every two people would wrongly believe himself or herself a carrier of the AIDS virus. This demonstrates that any positive result must be confirmed by a standard test. A test result alone is not enough to establish an individual diagnosis of HIV-contamination for a given person.

The Limits of Self-Analysis

In its 1988 opinion, the CNS emphasised that this type of self-test offers the ease and comfort of home-sampling. However, the self-test's drawback lies in the absence of pre- and post-test counseling sessions, intended first to inform about the risks of

contamination and the ways of preventing them, and secondly, to explain the meaning of the test and its result. The said sessions form the backbone of the screening system in France. Furthermore, they make it possible to provide support and follow-up to the person tested, particularly important when a positive result is announced. In order to become an integral part of an individual or group healthcare system, screening for HIV-contamination requires a direct relationship with a physician. Self-tests provide only a result which, as shown above, cannot provide a definite and final diagnosis. As the CNS has already pointed out, self-analysis tests do not encourage the subject to enter the healthcare system, leaving the user alone with the results.

Unethical Use

When a test is easy to use, regardless of how reliable it is, the risk of it being used in coercive situations is greater. For instance, the test could be performed by employers during the hiring process, insurers prior to signing a contract, police officers during checks, etc. Another use – to be feared – is that prior to sexual interaction, to justify not using means of prevention, thereby heightening the current surge in sexually transmitted diseases. The development of self-tests on the other side of the Atlantic is due in particular to the fear of losing one's anonymity. In France, where the law guarantees confidential access to screening and anonymised data processing, screening kits are not as valuable.

Conclusion

Self-testing, in addition to offering low diagnostic value, cannot be integrated into a broader prevention policy. Moreover, it leaves individuals to face positive results on their own, thus not fostering their seeking medical and social care, and creates risk of inappropriate use, going against individual rights. Above and beyond HIV self-testing, the objections raised in this opinion could also apply to other self-tests. For public health, medical, social and ethical reasons, the CNS warns against the distribution of self-tests for HIV-infection screening.

1. Opinion on "the opportuneness of making home HIV-screening tests available on the French market", **19 June 1998**.

2. Such kits, available online, are based only on blood samples, not saliva.

3. This label is required prior to any form of commercialisation in pharmaceutical outlets, as stated in the 1 March 2001 Order n° 2001-198 on the transposition of Directive 98/79/EC of the European Parliament and Council of Europe, dated 27 October 1998 regarding medical in vitro diagnosis devices.

4. In the CDC (Centers for Disease Control) study on the ability of people with no laboratory experience to carry out a self-test, only 9% failed to successfully carry out the test.

5. The median interval is 22 days.

6. Number of cases of new and already-reported illness in a given population, compared to population studied.

7. The specificity of a diagnostic test is its ability to yield a negative result if there is no illness.

8. The sensitivity of a diagnostic test is its ability to yield a positive result if there is illness.

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ANNEX 2

EUROPEAN RECOMMENDATIONS

• Recommendation 6 on medical genetic testing and its context:

6a. that “medically relevant genetic testing be considered an integral part of health service provision”;
6d. that “national healthcare systems ensure that genetic testing will be accessible equitably to all who need it”.

• Recommendation 7 on quality assurance:
7c. that “national healthcare systems establish consistent quality requirements for genetic testing”.

• Recommendation 9 on genetic counselling:
9a. that “in the context of healthcare, genetic testing be accompanied by the provision of key information and, where appropriate, by the offer of individualised counselling and medical advice (in the case of highly predictive genetic tests for serious disorders, the offer of specific counselling should be mandatory, and patients should be strongly encouraged to take advantage of it)”
9c.that “specific qualifications and quality standards for those engaged in the provision of specific genetic counselling, whether clinicians or non-clinicians, be established and made mandatory”.

• Recommendation 17 on the regulatory framework:

17a. that “the regulatory framework for genetic testing be further developed..."

17b. that “all newly developed tests must conform to the standards established before introduction into clinical use, based on a review process by an organisation or body independent of the test developer to ensure that the patient will benefit from the test”.