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## Quality criteria for health checks: Development of a European consensus agreement



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## ABSTRACT

**Objective.** Health checks may empower individuals to take better care of their health, but they may incorporate risks of incorrect test results, overdiagnosis and overtreatment as well. Some health checks are strictly regulated, such as in many of the national screening programs, but the ones offered outside such programs and in the commercial domain, are not. We developed a European consensus agreement for quality criteria.

**Method.** Quality criteria were developed with the contribution of 43 experts from 16 European countries and 8 European organizations. A working group drafted a proposal, which was revised in several rounds of internal and external review by a multidisciplinary group of experts.

**Result.** The quality criteria address the provision of information, communication and informed consent, predictive ability and utility of the test, and quality assurance.

**Conclusion.** The consensus agreement on the quality of health checks aim to enhance informed decision making in clients and protects the affordability of the health care system. The criteria can be developed further into a formal standard and regulation if such authority is warranted.

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## Introduction

People are increasingly interested in taking health checks to prevent or early detect diseases or to be reassured about their health status. A health check is a service providing information, interpretation and guidance around the offer and conduct of one or more tests. Examples of tests include questionnaires on health-related behavior and family history, physical examinations, psychological assessment, imaging and laboratory tests on biomarkers. Health checks are offered by health care professionals but also by employers, health insurance companies, private clinics and companies.

Health checks may improve health outcomes, promote awareness about good health and encourage healthy behavior. Yet they can have

*Abbreviations:* CEN, Comité Européen de Normalisation; EPAAC, European Partnership for Action Against Cancer.

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adverse consequences as well, especially when wrongly or inappropriately applied. ‘Normal’ test results might encourage people to be complacent about unhealthy behavior, the ‘clean bill of health’ effect (MacAuley, 2012); false positive results and overdiagnosis (true positives that otherwise would not have been detected) may lead to unnecessary diagnostic procedures and overtreatment (Kroggsboll et al., 2012); false negative results may lead to false reassurance; and tests themselves may carry health risks, such as complications from invasive tests and imaging techniques conducted with radiation. The balance between harms and benefits can be precarious. Scientific evidence on the benefits and harms of health checks is scarce (Si et al., 2014).

Different regulations and guidelines are in place to ensure an appropriate balance between benefits and harms of health tests. The European Directive 98/79/EC for in vitro diagnostics, for example, regulates the offer of self-tests, health tests that people can use at home without any service (1998). European and national guidelines regulate health checks that are systematically offered to the population at large such as the NHS health check (2010), new-born screening programs,

and screening programs for breast, cervical and colorectal cancer (Arbyn et al., 2008; Perry et al., 2006; Segnan et al., 2010). There are no specific guidelines for health checks that are offered to individuals outside the regulated programs.

The aim of quality criteria for health checks is two-fold: they should promote autonomous and informed decision making in clients and encourage providers to provide only those services that are effective in the prevention and early detection of health risks and disease, with arguably positive balance between benefits and harms. This article describes the development of a European consensus agreement on quality criteria for health checks.

**Methodology**

*Procedure*

The development of the quality criteria for health checks was initiated by the Dutch Ministry of Health, Welfare and Sport in collaboration with the European Partnership for Action Against Cancer (EPAAC). The quality criteria for health checks were developed following the standard procedure for consensus documents of the 'Comité Européen de Normalisation (CEN). CEN consensus agreements have no legal status and their implementation is not mandatory. They represent expert opinion consensus in areas where scientific evidence is scarce and therewith are important first steps to agenda setting, raising awareness and starting public debate on evolving topics of potential societal impact.

Table 1 presents the eight steps of this procedure. Participation was open to all interested stakeholders, and both an internal and an external review process were part of the procedure. The kick-off meeting was attended by 28 experts from 10 European countries (Austria, Belgium, Finland, France, Germany, Ireland, Netherlands, Poland, Slovenia and Switzerland) and 8 European institutes and organizations. Experts included representatives from patient organizations, industry and regulatory bodies, health care professionals and health researchers. The call for source documents and the survey for examples of health checks were additionally answered by representatives from 6 countries (Latvia, Norway, Romania, Slovakia, Spain and the United Kingdom). The selected source documents mention criteria for the evaluation of e.g., medical tests and technologies, genetic tests and population prevention programs. The source documents were used by the project team (the authors of this article) to develop a first working draft and to assure that the proposed criteria are in line with existing criteria for related health tests and technologies. The source documents are listed in Annex C of the workshop agreement (see reference below). The project team identified the main topics and selected relevant items from the source documents for each of them. Examples of health checks in the survey include a diabetes risk questionnaire offered via the internet in the Netherlands, a Gesundheits-check offered by general practitioners in Germany and a health screening offered by employers in Finland.

The first draft of the quality criteria was presented and discussed in the second plenary workshop meeting (first internal review), and the revised version was posted publicly to seek comments from a wider group of experts (external review). Fifty-eight comments were submitted, which were mostly related to refining definitions of the concepts used in specific criteria. These comments were discussed and approved during the third plenary workshop meeting (second internal review). The final version was published by CEN (CWA 16642 Health care services—Quality criteria for health checks) and is available from all national standardization institutes and via the EPAAC website ([www.epaac.eu](http://www.epaac.eu)).

A total of 43 experts contributed to one or more steps in the development of the criteria. These experts represented health policy agencies (n = 14), health research (n = 10), public health professionals (n = 8), industry (n = 4), patient advocacy organizations (n = 4) and medical professionals (n = 3). The competencies of the experts were diverse and included medicine, public health, health policy, law, health technology assessment, epidemiology, insurance, public health ethics, quality of care, education, patient advocacy and commerce. During the kick-off meeting, participants agreed that all relevant competencies were available, but that the insurer and payer perspective was underrepresented.

*Scope and definitions*

A health check was defined as a service offering one or more tests to individuals for the detection of one or more conditions or risk factors. This definition distinguished health checks from self-tests, which do not include service.

The working group aimed to develop generic criteria that apply to all health checks, but acknowledges that certain health checks are already regulated. These include national screening programs, such as cancer screening programs and prenatal screening, and self-tests, which are already covered by national and European guidelines and regulations. Also indicated testing, offered within the health care system as part of clinical care, is already covered by professional guidelines and falls outside the scope of the criteria proposed here.

**Results**

The working group specified criteria for the provision of information (domain 1), communication and informed consent (domain 2); the predictive ability and utility of the test (domains 3–7); and quality assurance (domain 8). Table 2 presents the domains as well as a summary of their items.

The provision of information, communication and the informed consent (domain 1 and 2) aim to ensure that clients have access to all information they need to make informed decisions about undergoing the health check. This information needs to cover all relevant aspects, and be understandable, timely, verifiable, accurate, complete, truthful and

**Table 1**  
Procedure steps in the development of the consensus agreement on quality criteria for health checks.

Procedure step	Aim	Form	Timeline
Announcement of the workshop	Invite EU stakeholders to participate in project	Online posting on CEN and EPAAC websites, email to stakeholders	August 2011
Workshop kick-off	Approve work plan; select project team, workshop chair and secretariat	Meeting, 1 day	December 2011
Survey and call for source documents	Collect information about health checks in EU	Online posting on CEN and EPAAC websites, email to stakeholders	January 2012
Project team meeting	Prepare draft quality criteria	Meeting, 2.5 day	April 2012
Workshop meeting	Internal review 1: Discuss draft	Meeting, 1 day	August 2012
Public enquiry	External review: Invite comments and suggestions on draft criteria from non-participants	Online posting, 60 days	October 2012
Workshop meeting	Internal review 2: Approve, amend and reject comments and suggestions; approve final version of criteria	Meeting, 1 day	March 2013
Publication CEN Workshop Agreement	Disseminate criteria	Online posting on CEN and EPAAC websites	June 2013

EU, European Union; CEN, Comité Européen de Normalisation; EPAAC, European Partnership for Action Against Cancer.

**Table 2**  
Quality criteria for health checks: the eight domains and a summary of their items.

<b>1. Information</b>
The provider shall provide information that is understandable, timely, verifiable, accurate, complete, truthful and not misleading (1.1) about the health check (1.2) and its potential results (1.3), in a way that enables the client to make an informed choice about the health check (1.4).
<b>2. Communication and informed consent</b>
The provider shall verify if the information requirements of the client are met (2.1), inform about the handling of any residual material from the test (2.2), inform about complaints procedures (2.3), obtain explicit informed consent (2.4), specify the findings consented (2.5), and provide sufficient time and opportunity for the client to reconsider the health check (2.6).
<b>3. Condition and target population of the health check</b>
The provider shall specify what is addressed by the health check, including the condition, natural course and seriousness, risk factors, symptoms, available treatment and follow up (3.1), define the purpose of the health check and the criteria of the target population, provide a personalized risk assessment, and the rationale for whether or not to use the test (3.2).
<b>4. Test procedure</b>
The provider shall specify the test, procedure, purpose, available test alternatives, burden and harms of test (procedure), analytic sensitivity and specificity, and reliability (4.1); define and implement clinical practice guidelines/protocols to carry out the test (4.2); and analyze the test results in accordance with available and established protocols (4.3).
<b>5. Test clinical validity</b>
The provider shall specify the cut-off value that defines positive and negative test results, clinical sensitivity and specificity, positive and negative predictive value, and positivity rate (5.1).
<b>6. Results</b>
The provider shall specify the test results, including the interpretation of the result, associated uncertainties of the test and followed protocols (6.1) in a written report (6.2).
<b>7. Follow-up</b>
The provider shall advise the client on further strategies to reduce the risk of acquiring the condition(s) or its negative consequences (7.1) following established protocols used in the health care system (7.2), and explain and document benefits, harms and costs of these recommendations (7.3).
<b>8. Quality and safety management and legal environment</b>
The provider shall establish an integral service around the health check fitted to the needs of the target population (8.1), establish, implement, maintain and continually improve management systems (8.2), respect national/European laws pertaining use and disposal of residual material (8.3), and provide evidence that management systems are in place (8.4).

not misleading. The provider might outsource the provision of such information, e.g., by referring to health websites, but remains fully responsible for the contents and quality. The provider has the responsibility to verify that the client has adequate understanding of what constitutes the health check and what the potential consequences of the test results are.

To enable informed decisions, clients need to have access to information about what is tested, for whom the test is intended, including an assessment whether it is intended for them, and for what reasons they should use the test (domain 3). They need access to information about what exactly will be done, how reliable and predictive the test is, and what possible adverse effects the test or the follow up procedure might have (domain 4 and 5).

The client needs to receive a written report containing the results, the interpretation and (if available and necessary) further strategies to reduce or manage the risk of the condition that is tested for (domain 6 and 7). The interpretation of the results as well as the recommendations for follow-up strategies should follow established protocols or professional guidelines to ensure responsible care.

Finally, the provider of the health check should ensure that the management of the service provision meets existing nationally and internationally accepted requirements as well as recognized quality, safety and information security requirements (domain 8). The quality

requirements address issues on the planning, monitoring and evaluation of the service; patient safety requirements address issues of how to deal with and prevent errors that could harm the client; and information security requirements address issues of accuracy and confidentiality. The provider can outsource certain aspects of these requirements but remains responsible.

## Discussion

In the development of the quality criteria, the working group came to strong consensus on three guiding principles. First, individuals should have access to adequate and sufficient information to make an informed decision about health checks. Therefore, the criteria specify what constitutes adequate information and informed consent (domains 1 and 2), and what topics need to be covered (domains 3 to 7).

Second, the quality criteria should improve beneficence in prevention and early detection of health risks and disease and protect individuals against potential adverse consequences (maleficence) of health checks. Because it is impossible to define specific requirements for the minimum predictive ability of the test or the availability of treatment options that apply to all health checks, we propose that the interpretation of the test and subsequent recommendations should be in line with health care standards or professional guidelines. In particular, the working group agreed that access to health care should be based on and restricted to tests and test results that meet protocols and professional standards that are used in the health care system. After all, physicians need to know how to handle the results of health checks and provide the best, and evidence-based, follow-up of the results.

And third, the criteria should ensure the quality of the health checks in the broadest sense. This principle led to the inclusion of specific criteria about the quality of the service and the establishment of management systems to ensure the quality, safety and information security (domain 8).

In the development of the criteria, the unnecessary use of valuable health care resources was a major concern. Health tests that have poor predictive ability or reliability yield high numbers of false positives and unnecessary follow-up consultations, and health checks for conditions that infrequently give symptoms lead to overdiagnosis and overtreatment (Bangma et al., 2007; Reid et al., 1998). Individual clients might consider these consequences acceptable, but flawed health tests put a considerable burden on the health care system when the use of health checks increases. Studies have shown that health checks may increase the number of diagnoses for chronic diseases and increased use in medication for high blood pressure with no impact on morbidity and mortality (Krogsboll et al., 2012).

The quality criteria for health checks were developed on the basis of existing criteria and guidelines, such as the widely used Wilson and Jungner criteria for population based screening (Wilson and Jungner, 1968) and the ACCE framework for the evaluation of genomic tests (Haddow and Palomaki, 2003). They largely overlap, but differ in details due to the differences in aims and scope. The Wilson and Jungner criteria require, among other things, that the condition is an important public health concern, that the test should be available to the population at large, and that the cost of the program should be balanced in relation to possible expenditure on medical care as a whole. The quality criteria for health checks developed in this project go beyond these general aims; they aim to promote autonomous informed decisions by clients and require description of the condition and the target population, and clear information about the harms and costs.

The workshop agreement is a consensus document by a diverse group of stakeholders across EU member states, composed through several rounds of internal and external consultations. The agreement has no legal status; providers of health checks are not obliged to adhere to these criteria. Rather, together with reviews that have demonstrated the lack of scientific evidence for health checks (Krogsboll et al., 2012), the workshop agreement can be a starting point for further discussion

on the desirability and feasibility of regulation and monitoring of the quality of health checks that are not yet regulated.

Efficient and effective regulation and monitoring of the quality of health checks will undoubtedly be a challenge. The offer of health checks is broad and diverse, coming from both health care organizations as well as the commercial industry. Yet, providers of health checks and follow-up examinations (health care organizations and industry), users (consumers and consumer organizations) and payers (health insurance companies and governments) all have good reasons to demand quality and quality standards. Together with regulatory agencies, such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), they could work toward feasible solutions for the regulation of this upcoming market. In light of the cross-border offer of many health checks, discussion and collaboration on an international level is advised.

## Conclusions

Given the concerns about the quality and limited impact of health checks, it is in the interest of protecting individuals and of keeping the health care system accessible and affordable that further steps are taken to ensure the quality of health checks. The proposed criteria can be a starting point for further discussion.

## Conflict of interest

The authors declare there is no conflict of interest.

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