Health care services - Quality criteria for health checks

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

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Foreword

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2013-02-08, the constitution of which was supported by CEN following the public call for participation made on 2011-08-31.

The CEN Workshop offers a platform whereby stakeholders can discuss and resolve standardization issues by consensus and validation in an open process.

The main activity of a CEN Workshop is the development and publication of the CEN Workshop Agreement (CWA). The CWA is a voluntary standard applicable internationally and does not have the force of regulation. A CWA can be an initial step in the development of a European standard.

The development of CWA 16642 Quality criteria for health checks has received funding from the Ministry of Health, Welfare and Sport, the Netherlands and the European Platform Action Against Cancer (EPAAC). CWA 16642 is also available from the EPAAC website: www.epaac.eu.

The secretariat was held by the Dutch National Standards Body, NEN. A list of the individuals and organisations which supported the technical consensus represented by the CEN Workshop Agreement is available to purchasers from the CEN-CENELEC Management Centre. These are listed below:

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The formal process followed by the Workshop in the development of the CEN Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of the CEN Workshop Agreement or possible conflict with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its members.

The final review/endorsement round for this CWA was started on October 2012 and was successfully closed on December 2012. The final text of this CWA was submitted to CEN for publication on May 2013.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of The following countries: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN-CENELEC Management Centre.
Introduction

Quality criteria for health checks

There is an increasing interest among the public to proactively take medical tests and undergo medical check-ups for preventing disease or detecting the presence of disease. In response to the growing interest, the supply of health checks is rapidly increasing within the regular health care services, but even more in the private/commercial domain.

Health checks are services that offer one or more examinations with the aim of detecting a condition or risk factor. Health checks can be offered by health care professionals, such as general practitioners, but also by employers, health insurance companies, patient organizations, non-governmental organizations, private clinics and companies. The service typically includes pre-test information, the actual testing and post-test interpretation of results. The tests that are used can be, but are not limited to, self-report questionnaires on health-related behaviour and family history, physical examinations, psychological assessment, imaging and laboratory tests on biomarkers.

Health checks may have many advantages. Health checks can improve health outcomes if conditions or risk factors are discovered in a stage that still allows for prevention or management of symptoms and they can make people aware of the risks to their health, thus allowing them to adjust their life styles. But health checks have disadvantages as well. Health checks incorporate a serious risk of unnecessary medical procedures and may lead to an unwanted rise in medical expenses, due to a high number of false positive results, overdiagnosis and overtreatment; or false reassurance in case of false negative results. Furthermore, some tests may carry risks in themselves, such as invasive tests or imaging techniques conducted with radiation. The balance between advantages and disadvantages is often precarious.

To promote an appropriate balance between the advantages and disadvantages many national and European regulations and guidelines are in place. For example, in vitro diagnostics, the tests that are often used within health check services, are regulated by Directive 98/79/EC. The Council of the European Union has recommendations for national screening programmes. The European Union has published quality assurance guidelines for screening for breast-, cervical and colorectal cancer [1-4]. Many governments have quality assurance guidelines for the national programmes or population based screening programmes such as newborn screening programmes and the statutory health check-up. Under these regulations, the risks and benefits of health check programs are weighed.

This Workshop Agreement does not aim to discuss or replace the criteria used to guide the (already) regulated health checks or (population based) screening programmes. Health checks frequently concern services that are not covered by these regulations. Directive 98/79/EC only refers to products and does not cover the service the tests are used in. Regulations for national screening programs do not only weigh the pros and cons of the test, but also whether there is an important public health problem, health service provisions are made for follow up, it is cost effective (Wilson and Jungner criteria for population screening [5]). Specific criteria for the offer of health checks to individual clients currently do not exist.

Criteria for health checks offered to individual clients may have many similarities with existing regulations, but require adjustments as well. Cost-effectiveness may not be a relevant criterion, but we should address the impact of using the tests to guide other actions, such as starting treatment or life style change, and examine the downstream consequences such as anxiety and overtreatment. Also, for individual decision making, additional criteria may apply for information and informed consent.

This Workshop Agreement Quality criteria for health checks is mainly aimed at providers of health checks and policy makers. Providers might learn what defines a responsible health check service and improve their services accordingly. Policy makers might learn to decide about the need for policy or regulations for all or specific health checks, or providers. Quality criteria for health checks will help consumers to make informed
choices. The aim of this workshop agreement on health checks is to provide a basic set of quality criteria to be built upon and help to meet these requirements.
1 Scope

This CEN Workshop Agreement (CWA) describes the basic principles of quality criteria for health checks.

Quality criteria for health checks aim:

— to allow clients to make informed choices about health checks,
— to improve beneficence in prevention and early detection of health risks and disease,
— to protect individuals against potential adverse consequences (maleficence) of health checks and
— to ensure the quality of the health checks.

Although the CWA aimed for a set of generic criteria, outside the scope of the CWA are:

— screening services covered by the recommendations of the Council of the EU on cancer screening,
  EXAMPLE The European Union has published quality assurance guidelines for screening for breast-, colorectal and
  cervical cancer [1-4].
— health checks, national screening programmes or other preventive and prophylactic services already
  regulated by national or EU legislation and rules,
  EXAMPLE Prenatal screening programmes and the statutory German health check-up comply with national
  regulations.
— products such as self-tests already covered by national or EU legislation and rules,
  EXAMPLE Self-tests such as pregnancy tests are covered by Directive 98/79/EC.
— indicated testing as offered within the health care system.
  EXAMPLE Genetic testing for Huntington's disease is indicated when one or more family members are affected.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1 analytical sensitivity
probability that the test result is positive when the measurand is present

2.2 analytical specificity
probability that the test result is negative when the measurand is absent

2.3 analytical validity
ability of a test to measure the characteristic that it was designed to measure, indicated by a combination of
the analytical sensitivity and analytical specificity
2.4 analytical assessment
assessment of the characteristic that is used to indicate the likelihood or presence of the condition or risk factor

EXAMPLE Blood pressure measurement, DNA testing and online questionnaires

2.5 beneficence
doing good, done for the benefit

Note 1 to entry Beneficent health checks help prevent or remove harms or to simply improve the condition.

2.6 client
individual, user, participant, consumer of a health check

2.7 clinical practice guideline
set of systematically developed statements, preferably based on scientific evidence, to assist clinical decision making

2.8 clinical sensitivity (or true positivity rate)
probability that the test result is positive in individuals who do or will have the condition or risk factor

2.9 clinical specificity
probability that the test result is negative in individuals who do not or will not have the condition or risk factor

2.10 false negative result
negative test result in a person who does or will have the condition or risk factor that is tested for

2.11 false positive result
positive test result in a person who does not have or will not have the condition or risk factor that is tested for

2.12 guideline
recommended approach for utilizing a product or conducting an activity or task

2.13 harm
any adverse consequences (e.g. physical or psychological) to a person that interferes with the health or comfort of the person that proportionally is more than merely transient or trifling in nature

2.14 health care system
organisation of people, institutions and resources to deliver health care services to meet the health needs of the population

2.15 health check
service offering single or periodic examinations to detect a condition or risk factor

Note 1 to entry CWA 68 describes what is included in the service of offering health checks.
2.16 incidence
number of new cases occurring within a population within a specified period of time

2.17 information
meaningful data

2.18 maleficence
causing or capable of producing harm

2.19 management system
system for organizations to develop and manage their policies, processes and procedures to achieve specific objectives

Note 1 to entry A management system of an organization can include different management systems, such as quality management system, patient safety management system, information security management system, environmental management system.

2.20 (medical) test
assessment of a characteristic that is used for prediction, diagnosis or prognosis of the condition or risk factor

Note 1 to entry Medical tests can be used for monitoring the treatment response, but this is outside the scope of this document.

2.21 national screening programme
system of services for the prevention or early detection of (specific) conditions organized at national level

2.22 natural course
what would happen to the condition in the absence of any intervention

2.23 negative predictive value
probability that an individual does not or will not have the condition or risk factor that is tested for, when the test result is negative

2.24 negative test result
value or range of values of the characteristic that indicate that the individual has a lower probability of or does not have the condition or risk factor that is tested for

2.25 overdiagnosis
diagnosis of condition that will never cause complaints

2.26 overtreatment
medical interventions that do not improve the health outcome of a condition or that cause unnecessary health burden

2.27 personalized risk assessment
analysis and evaluation of a client's risk of developing the condition or risk factor that is tested for.
Note 1 to entry The purpose of a personalized risk assessment is to determine whether the client belongs to the target population for the health check.

2.28 population based screening programme
system of services for the early detection and treatment of (specific) conditions that is offered to all eligible people in the population at large or an entire subgroup of the population

EXAMPLE All women between 50 and 75 years of age are offered mammography screening.

2.29 positive predictive value
probability that an individual has or will have the condition or risk factor that is tested for when the test result is positive

2.30 positive test result
value or range of values of the characteristic that indicate that the individual has a higher probability or has the condition or risk factor that is tested for

2.31 positivity rate
probability that the test result is positive

2.32 prevalence
the number of individuals with a condition or risk factor in a population at a specific point in time

Note 1 to entry A population can for instance refer to an age group or women or men separately.

2.33 procedure
specified way to carry out an activity or a process

2.34 protocol/ professional standard
documented agreement between practitioners on the diagnostic or therapeutic clinical practice guideline that for a certain group of clients on average will lead to the optimal result

2.35 provider/ health check provider
public, private or public-private sector organization that carries out the health check

2.36 quality management
coordinated activities to direct and control an organization with regard to quality

2.37 reliability
ability of the test to yield the same results in independent assessments

2.38 risk
combination of the probability of an event and its consequence

2.39 target population for the health check
specified group of people for which the health check has demonstrated clinical validity to indicate the risk of the condition or risk factor
3 Quality criteria

NOTE In CWA 68 condition and risk factor can refer to multiple conditions and risk factors.

3.1 Information

The provider shall provide information that is understandable, timely, verifiable, accurate, complete, truthful and not misleading.

The provider shall provide information on the aim, benefits and harms and potential adverse consequences of the health check, the prevalence and incidence of the condition or risk factor searched for, the target population for the health check, the potential positive and negative results and options, costs and consequences of follow up of the health check offered.

The provider shall provide information on any (clusters of) parallel findings that might occur as a (direct or indirect) result of the health check, including their benefits and harms, prevalence and incidence.

EXAMPLE Applicants of a life insurance or mortgage may need to state known illnesses. An unexpected or presymptomatic diagnosis can have adverse consequences for insurances and mortgage.

The information should enable the client to ascertain the presence or absence of balance between benefits and harms of the health check for target or age group and make an informed choice about the personal usefulness of the health check.

3.2 Communication and informed consent

The provider shall verify if the information requirements of the client as stated in 3.1 are met and tailor further communication to those needs.

The provider shall inform the client on what will happen with the residual material from the test and get informed consent if this material and/or data is used for other purposes than the test only.

The provider shall explain the complaints procedure to the client, including available insurance coverage.

The provider shall ensure that the client has given explicit informed consent before performing a health check.

The provider shall specify for what findings the client gives consent and will respect the right not to know (clusters of) incidental or parallel findings that might occur as a (direct or indirect) result of the health check.

The provider shall provide sufficient time and opportunity to the client to reconsider performing the health check, proportional to the condition the health check aims for (either directly or indirectly via risk factor).

NOTE Annex A provides an example of an Informed consent tool.

3.3 Condition and target population

The provider shall specify what is addressed by the health check, including:

— which condition it is aimed for (either directly or indirectly),
— what is the natural course and seriousness of the condition,
— which are the known risk factors for acquiring the condition,
— what are the symptoms at different stages of the condition,
— what treatment or follow up is available for the condition or risk factor,
— how the health check and follow up can alter or cannot alter the natural course of the condition or risk factor.

The provider shall define the purpose of the health check.

The provider shall define the in- and exclusion criteria of the target population for the health check.

The provider shall provide a personalised risk assessment and ascertain whether the client meets the inclusion criteria and does not meet the exclusion criteria of the target population.

The provider shall provide sufficient rationale and document in case the use of the test deviates from the standard use or the intended population.

3.4 Test procedure

The provider shall specify:

— the test and test procedure,
— the purpose (analytic assessment and clinical purpose),
— available alternatives to the test,
— the burden and harms of the test and test procedure,
— the analytic sensitivity and specificity and reliability.

When specifying alternatives, the alternative of not doing the health check should be included.

The provider shall define and implement the clinical practice guidelines and protocols to carry out the tests.

The provider shall analyze the test results in accordance with available and established protocols and motivate and document when and why established protocols are not used. The provider shall explain and document possible benefits and harms of any deviations from established protocols.

3.5 Test clinical validity

The provider shall specify:

— the cut-off value that defines positive and negative test results,
— the clinical sensitivity and specificity,
— the positive and negative predictive value,
— the positivity rate.

3.6 Results

The provider shall specify the test results, including:

— the interpretation of the result,
— the associated uncertainties of the test and followed protocols,
— any parallel findings, if consented beforehand.
The provider shall provide a written report of result(s), interpretation and uncertainties and possibilities for follow-up.

### 3.7 Follow-up

The provider shall advise the client on strategies the client can follow to reduce any further risk of acquiring a condition(s) or its negative consequences.

The provider shall follow established protocols/professional standards used in the health care system for follow-up.

**NOTE** The use of the same protocols and professional standards in the health care system as well as in follow-up or referral by health check providers is a measure to prevent confusion in clients about the interpretation of test results, overdiagnosis and overtreatment.

The provider shall motivate and document when recommendations do not follow established protocols/professional standards. Recommendations shall be safe and realistic. The provider shall explain and document benefits, harms and costs of these recommendations.

### 3.8 Quality and safety management and legal environment

The provider shall establish an integral service around the health check in compliance with all components mentioned in 3.1 to 3.7 and fitted to the needs of the target population.

The provider shall establish, implement, maintain and continually improve management systems, according to recognized national/European or international standards, for:

- quality management,
- client/patient safety management and
- information security management.

**NOTE** Annex B provides examples of quality management system standards and the topics included in such a quality management system.

The provider shall respect national/European laws pertaining use and disposal of residual material.

The provider shall provide evidence to the client that national/international recognized quality-, client-/patient safety and information security management systems are in place.
Annex A
(informative)

Informed consent tool

If you are offered a health check, or if you want a health check, you should answer these questions before deciding. When you answer all questions with yes, you are informed:

<table>
<thead>
<tr>
<th>Question</th>
<th>yes</th>
<th>no</th>
</tr>
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<tbody>
<tr>
<td>1. Did the provider explain why this health check may be appropriate for me?</td>
<td></td>
<td></td>
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<tr>
<td>2. Did the provider inform me about the evidence for the test and the uncertainties?</td>
<td></td>
<td></td>
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<tr>
<td>3. Did the provider explain about benefits and harm? Also about any possible parallel findings that might occur?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Did the provider verify if I understood all information and everything I needed to know or did not want to know?</td>
<td></td>
<td></td>
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<tr>
<td>5. Did I get a written contract?</td>
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<tr>
<td>6. Did the provider guide me with a decision aid that I understood and found applicable for my needs?</td>
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<tr>
<td>7. Did the provider NOT pressure me to take the health check (e.g. with advertising or disproportionate use of my apparent concerns)?</td>
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<tr>
<td>8. Did the provider give appropriate time and opportunity to reflect and reconsider?</td>
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<tr>
<td>9. Did the provider offer a second opinion or at least inform me in an unbiased way of the existence of alternative tests and/or providers?</td>
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<tr>
<td>10. Did the provider give information on the complaint procedure?</td>
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<tr>
<td>11. Did the provider supply me with information on the full cost of the health check and all components beforehand?</td>
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</tbody>
</table>

NOTE  This informed consent tool is adapted from [6].
EN ISO 9001:2008 [7] is an example of an international recognized standard on quality management systems. EN 15224:2012 [8] is an example of a European recognized standard on quality management systems for health care. The content pages of these standards provide an overview of the topics in a quality management system.

4 Quality management systems

4.1 General requirements – establish, document, implement and maintain a quality management system and continually improve its effectiveness

4.2 Documentation requirements – include quality policy and objectives, quality manual, procedures and documentation required to ensure planning, operation and control of its processes

5 Management responsibility

5.1 Management commitment – provide evidence of commitment to the development and implementation of the quality management system

5.2 Customer focus – determine customer requirements with the aim of enhancing customer satisfaction

5.3 Quality policy – ensure that the quality policy is appropriate to the purpose of the organization and includes a commitment to comply with the requirements and continually improves

5.4 Planning – ensure that the quality objectives are established at relevant functions and levels within the organization

5.5 Responsibility, authority and communication – ensure that the responsibilities and authorities for relevant roles are assigned and communicated

5.6 Management review – review the organization's quality management system to ensure its continuing suitability, adequacy and effectiveness

6 Resource management

6.1 Provision of resources – determine and provide the resources needed

6.2 Human resources – determine the competence of the personnel, ensure the competencies on the basis of appropriate education, training or experience

6.3 Infrastructure – determine, provide and maintain the infrastructure needed, such as building space and associated utilities, process equipment and supporting services

6.4 Work environment – determine and manage the work environment such as noise, temperature and lightning

7 Product (health care service) realization

7.1 Planning of product (health care service) realization – plan and develop the process needed for product (health care) realization
7.2 Customer-related processes – determine, review and communicate the customer requirements

7.3 Design and development – plan, control, verify and validate the development of the product and control the changes

7.4 Purchasing – ensure, monitor and verify that purchased products conform to specified requirements

7.5 Production and service provision – plan, carry out, monitor and verify production under controlled conditions such as work instructions, protocols, use of suitable equipment

7.6 Control of monitoring and measuring equipment – to ensure valid results measuring equipment is calibrated

8 Measurement, analysis and improvement

8.1 General – plan and implement the monitoring, analysis and improvements processes

8.2 Monitoring and measurement – monitor customer perception, conduct internal audits, measure and verify that product requirements are met

8.3 Control of non-conforming product (health care service) – ensure that non-conforming products or services are identified and controlled

8.4 Analysis of data – determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system

8.5 Improvement – continually improve the effectiveness of the quality management system including corrective and preventive actions
Annex C
(informative)

Source documents on quality criteria for health checks

The following documents were used as source documents for the development of CWA 68:


CVZ. Medische tests (beoordeling stand van de wetenschap en praktijk). 2011

EUNETHTA. HTA Core Model for screening technologies. 2011


Gezondheidsraad (Health Council of the Netherlands). Leidraad voor identificatie en bescherming van hoogrisicogroepen. 2011

Hoffman JM, and Poortvliet EP. Health Checks in Nederland. Een quick scan van het veld. 2010

Holland WW, Stewart S. and Masseria C. Policy Brief Screening in Europe. World Health Organization, on behalf of the European Observatory on Health Systems and Policies. 2006

NHS. Programme appraisal criteria. Criteria for appraising the viability, effectiveness and appropriateness of a screening programme. 2010


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