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Standard Recommendation
S.R. CWA 16642:2013

Health care services - Quality criteria for health checks

S.R. CWA 16642:2013

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CEN WORKSHOP AGREEMENT

CWA 16642

June 2013

ICS 11.020

English version

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.

The formal process followed by the Workshop in the development of this 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 this CEN Workshop Agreement or possible conflicts 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.

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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 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