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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.

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 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 (Krogsboll 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,

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

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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).

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.