



CEN Workshop Business Plan

“Health care services – Basic quality criteria for health checks” (CEN/WS 68)

(approved in the kick-off meeting on 2011-12-02)

Business Plan for CEN Workshop "Basic quality criteria for health checks" (CEN/WS 68)

1. Background to the CEN Workshop

The Council of the European Union recommends evidence-based, quality assured programmes of screening in adults for cervical-, breast- and colorectal cancer and standards and principles to be adhered to in making decisions on adoption or modification of cancer screening programmes (Council of the EU, 2003). For these programmes comprehensive, evidence based guidelines are available to enable responsible authorities to ensure quality and safety. The Council Recommendation on cancer screening also provides guidance on how to make decisions on the adoption of novel screening methods for the above-mentioned sites as well as for other potential target cancers.

Screening services provided by national health services in accordance with the Council Recommendation, such as publicly mandated national or regional screening programmes for cervical, breast and colorectal cancer are introduced on the basis of sound scientific evidence, are subject to ongoing scrutiny and provide continuity of care and follow-up.

Even though opportunistic screening is not recommended by the EU, it still occurs widely in many European countries (Karsa et al. 2008); sometimes in the context of health checks and sometimes outside this context in provision of other types of health services. Some of these opportunistic practices include the use of tests that are not recommended by the EU for cancer screening. There is variation in this respect between the Member States and efforts to improve health services in the EU should avoid activities which may encourage cancer screening practices which do not fulfill the internationally recognized European standards for cancer screening (European Commission, 2006; European Commission, 2008; European Commission, 2010).

Health checks and (periodic) health examinations are emerging for many diseases. For many of these checks a comprehensive evidence base is lacking, and many other long established quality criteria for screening are not met (Holland et al., 2006). Thus data on efficacy from randomized controlled trials, data on evaluating effectiveness of the service and monitoring data on the requisite performance indicators is not available.

For some people, effectively implemented health checks could theoretically prevent disability and death and improve quality of life. Noteworthy, a proportion of clients may also have some symptoms that may need further investigation. If early and accurate, diagnosis and intervention could lead to an improved prognosis. If treatment would need to be less radical, scarce health services resources would be saved by treating diseases before they progress and those with

true-negative test results could be reassured. Furthermore, in many countries activities/ interventions aiming to primary prevention of risk factors (such as overweight, hypertension, tobacco smoking, occupational exposures) are included in the health checks (Holland et al., 2006).

The theoretical disadvantages in early diagnosis issues associated with health checks are complex. There would be longer periods of morbidity for patients whose prognosis is unchanged and there may be overtreatment of non-serious conditions or detected abnormalities. There are also resource costs in finding more illness both in terms of the tests themselves, the personnel costs and the subsequent management of whatever is found. There is the unpalatable certainty that some individuals with false-negative results will be given unfounded reassurance and that some with false-positive results will experience, at the very least, unnecessary anxiety and, at the worst, inappropriate treatment. Finally, there is the possibility of hazard from the screening test itself.

Due to a lack of comprehensive standards similar to those developed for population-based cancer screening, health checks and (periodic) health examinations are an area which may potentially be unfavorably exploited by the private and commercial sectors (Holland et al., 2006).

In 2008 the Health Council in the Netherlands reported that a fresh approach is needed to encourage good practice across the broad spectrum of screening in health care and to protect individuals against the risks of unsound prophylactic examinations. A key element proposed by the Health Council would be to establish a quality-mark for responsible health checks, based on scientific assessments of new developments and aimed at promoting responsible provision and responsible choices (Health Council of The Netherlands, 2008). This is not feasible in the framework of the present project due to the depth and the breadth of scientific evidence that would be required to define such a quality mark, and because the reliable procedures that would be required to effectively implement it, are not yet developed. However, initial, methodologically sound steps are urgently needed to move forward in this area.

In 2011 the Executive Agency for Health and Consumers of the European Commission has therefore decided to award a grant for the action entitled 'European Partnership for Action Against Cancer'. The proposal 'Developing basic quality criteria for health checks' at European level is included in the work package 'Screening and early diagnosis'.

This Joint Action will result in a CEN Workshop Agreement (CWA) on 'Basic quality criteria for health checks'. CWAs are consensus-based specifications, drawn up in an open Workshop environment. A CEN Workshop Agreement is a more flexible and timelier alternative to the European Standard (EN), but one which still possesses the authority derived from the openness of participation and agreement inherent in the operations of CEN and its national members.

2. Workshop proposers and Workshop participants

Original proposers of the Workshop

The proposers of the workshop are:

- The Netherlands: Ministry of Health, Welfare and Sport.

Associated partners include:

- Germany: German National Association of Statutory Health Insurance Physicians;
- Ireland: Consultant Gastroenterologist, Trinity College;
- Espen and European Nutrition for Health Alliance.

Participants at the Workshop

Participation in the Workshop is open to anyone, and the opportunity to participate is widely advertised in advance by its proposers, in the European Partnership for Action Against Cancer (EPAAC, www.epaac.eu) and by CEN and its member bodies.

The invitation to the kick-off meeting is presented at the Joint Action Open Forum meeting in Madrid in June 2011. Simultaneously CEN published the CWA Business Plan "Quality criteria for health checks", which include the invitation through the CEN channel.

3. Workshop scope and objectives

The Workshop aims to achieve consensus on basic principles of quality criteria for health checks.

Health checks are single or periodic medical examinations offered to people to prevent or early detect one or more diseases or risk factors or poor health outcomes.

The Workshop will further elaborate on the definition of health checks.

Quality criteria for health checks aim:

- to encourage good practice in prevention and early detection of health risks;
- to protect individuals against the risks of unsound health checks;
- to allow clients to make responsible choices about health checks.

Outside the scope of the project are:

- a) screening services covered by the recommendation of the Council of the EU on cancer screening (e.g., screening for breast-, colorectal and cervical cancer and screening using potential new tests, e.g. screening for prostate cancer);
- b) health checks or other preventive and prophylactic services already regulated by national or EU legislation and rules (e.g. the statutory German health check-up);
- c) products such as self- tests already covered by national or EU legislation and rules (e.g. covered by directive 98/79/EG).

4. Workshop programme

At the start of the project relevant source documents will be sourced from the participating countries. Apart from The Netherlands also the UK, Ireland, Germany and Belgium have already expressed interest to participate in the project team. Many representatives from countries participating in the EPAAC have expressed interest to participate in the Workshop.

The programme to reach the CEN Workshop Agreement entails the following steps:

1. Organisation of the kick-off meeting

The CEN Management Centre (CCMC) will post the Business Plan, the invitation and the agenda for the kick-off meeting on the CEN Website for a period of 60 days. The interested parties will be able to register by email. In parallel, an invitation is presented at the Joint Action Open Forum meeting in Madrid in June 2011. Participation in the development of the CEN Workshop Agreement is open to anyone, and the opportunity to participate will be widely advertised in advance by its proposers, in the European Partnership for Action Against Cancer and by CEN and its member bodies.

2. The CCMC has organized the **kick-off meeting** in December 2011 to plan the CEN Workshop Agreement. The kick-off meeting:
 - approved the Workshop Business Plan;
 - selected the project team, Workshop chair and designate the secretariat;
 - solicited for source materials from the different participating countries.
3. The Workshop secretariat, on behalf of the project team, will distribute a survey on relevant source materials from the respective countries/organizations.
4. In the **preparatory meeting, the project team** will review source materials and prepare the first draft for workshop consideration.
5. The Workshop secretariat will organize the first **CEN Workshop plenary meeting** for all registered participants.
6. An internal reviewing period will be carried out to allow for inclusion of final comments from Workshop participants to ensure consensus is reached on the content.
7. A 60-day Public comment phase will be carried out.
8. A second plenary meeting for registered Workshop participants will be organised for the resolution of the comments received during the 60-day public comment phase.
9. The chairman will check by correspondence that a consensus has been reached on the final draft of the CWA.
10. When the consensus is met, the CWA will be sent to the CEN-CENELEC Management Centre for publication.

Work in progress

	Development of pan-European consensus on quality criteria for health checks	
	Preliminary activities before the launch of the Workshop Business Plan	Mar – Jun 2011
1	Invitation to the kick-off meeting during the Joint Action Open event in Madrid in June 2011	Jun 2011
2	Workshop Kick off meeting CWA open to any interested party	Dec 2011
3	Survey planned on availability of relevant source documents for the Workshop	Dec 2011- Feb 2012
4	Project team preparatory meeting , reporting on the applicability of relevant source documents	Mar/Apr 2011
	Report results of survey by the project team	Jun 2012
5	CEN Workshop Plenary meeting for registered participants	Sept 2012
6	Draft Report on Quality criteria for health checks and internal reviewing period	Oct - Nov 2012
7	Public comment phase on Draft CWA Quality criteria for health checks	Jan – Feb 2013

8	CEN Workshop Plenary meeting for registered participants for resolution of comments	Mar 2013
10	Publication CEN Workshop Agreement "Quality criteria for health checks"	May 2013

5. Workshop structure

The working language during the Workshop is English. The CWA will be drafted and published in English.

According to the requirements of the EC the draft documents and final CWA publication will be available through the EPAAC website free of charge. The documents on the EPAAC website will be identical to the documents available from CEN and, as such, will carry the CEN logo only.

The CWA will be published by CEN and made publicly available through the different Standardization Institutes in the member states at the normal costs.

6. Resource requirements

All costs related to the participation of interested parties in the Workshop's activities have to be borne by themselves.

The Executive Agency for Health and Consumers (EAHC) of the European Commission has awarded a grant for the Joint Action "European Partnership for Action Against Cancer". The proposal "Developing initial quality criteria for health checks at European level" is included in the work package "Screening and early diagnosis". Through this grant participating parties can apply for reimbursement of travel and subsistence costs. In case of shortage of funds preference will be given to refund travel and subsistence costs of representatives from public parties and NGOs.

7. References

Council of the European Union (2003), Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC), Off J Eur Union no. L 327, pp. 34-38.

European Commission. European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, & von Karsa L (eds.) Office for Official Publications of the European Communities, Luxembourg, 2006.

European Commission. European guidelines for quality assurance in cervical cancer screening - second edition. Arbyn M, Anttila A, Jordan J, Ronco G, Schenck U, et al., (eds.). Office for Official Publications of the European Communities, Luxembourg, 2008.

European Commission. European guidelines for quality assurance in colorectal cancer screening and diagnosis - First edition. Segnan N, Patnick J, von Karsa L (eds.) Publications Office of the European Union, Luxembourg, 2010.

Health Council of The Netherlands. Screening: between hope and hype. 2008.

Holland WW, Stewart S, Masseria C. Screening in Europe, Policy Brief 10. World Health Organization/European Observatory of Health Systems and Policies, Geneva, Switzerland, 2006.

NHS UK National Screening Committee. *Criteria for appraising the viability, effectiveness and appropriateness of a screening programme*. 2009.

von Karsa L, Anttila A, Ronco G, Ponti A, Malila N, et al. Cancer Screening in the European Union. Report on the implementation of the Council Recommendation on cancer screening - First Report. European Commission, Luxembourg. 2008.

www.cen.eu

www.epaac.eu

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