
Executive summary

Health Council of the Netherlands. Checking checked: appropriate use of health checks. The Hague: Health Council of the Netherlands, 2015; publication no. 2015/05

In this advisory report, the Health Council of the Netherlands' Committee on Population Screening highlights the benefits and risks of health checks and makes recommendations concerning the associated protective role of the government. Health checks are medical tests that are intended to detect diseases (or the associated risk factors) in individuals without any relevant medical indication. One example is a total body scan. Some health checks are governed by the Population Screening Act (WBO) and at present cannot be carried out without a permit. The Minister of Health, Welfare and Sport wants to maximize people's freedom to choose whether or not to undergo a health check. She has asked the Health Council about the required conditions. What criteria must health checks meet and what requirements should the government impose to protect people against the risks involved in tests of this kind?

The impact of health checks on individuals

The benefits of health checks are often taken for granted. In scientific terms, however, these cannot so easily be established. Studies have shown that no health gains are to be expected, as far as reduced mortality and/or reduced morbidity are concerned at population level. However, this is not necessarily the case for specific subgroups. Furthermore, individuals may feel that reassurance (if no problems come to light) or merely useful information suffices to undergo a health

check. There hardly is any scientific evidence that this is indeed the case, and whether or not individuals actually benefit from such checks.

Yet the old adage “it doesn’t hurt to try” is hardly applicable to health checks. They certainly involve various major risks and drawbacks, although little is known about the extent to which these actually occur. For instance, a health check may well uncover an anomaly that would never have caused problems (overdiagnosis). Also there can be incidental findings whose implications, in terms of treatment and prognosis, are unclear. Furthermore, as with any type of medical treatment, there is a risk of complications and of erroneous results. In the latter case, false positive results can lead to further tests (possibly invasive in nature) and unnecessary treatment, while false negative results can lead to unwarranted reassurance and potential delays in the diagnostic process.

The impact of health checks on regular care and on society at large

The Minister has asked the Health Council for details of the conditions under which health checks might be offered by hospitals and other regular healthcare providers. One advantage of conducting health checks within the context of regular health care is that it might then be possible to dovetail them into the rest of the healthcare system more simply and effectively. Given the huge differences between indication-driven healthcare and health checks, however, the drawbacks involved might well be too large. For instance, specialists would have to take dedicated refresher courses to enable them to perform qualitatively responsible health checks. If patients are not fully capable to distinguish between indication-driven healthcare and health checks, they would likely tend to overestimate the value of hospital-based health checks. This effect would be further enhanced if insurers – as agents of care with a favourable price-quality ratio – were to include health checks in their supplemental insurance policies. This would boost demand for health checks, resulting in higher healthcare costs and problems of undercapacity. Accordingly, in its advice to the Minister, the Committee recommends that health care and commercial health checks be kept separate.

One leading question is what impact the increasing use of health checks will have on the healthcare system. It is plausible to assume that health checks tend to generate follow-up costs and waiting lists. Nevertheless, there is a lack of quantitative data about the potential scale of these consequences in case of a more generous policy concerning health checks. That would also depend on the specific details involved, for example on whether insurers were to include health

checks in their supplemental policies. The Committee recommends to perform research into these effects. Increase in healthcare costs and waiting lists as a consequence of health checks might undermine the foundation of justice and solidarity on which our healthcare system is based.

The government's responsibility

According to the Constitution, the government is required to take measures to promote public health. This includes the duty to ensure responsible provision and appropriate use of health checks. The government must provide protection against the drawbacks and risks of health checks without interfering unnecessarily in the individual's freedom of choice. The government's duty of protection consists of three elements.

Firstly, the government should ensure that health checks are provided and implemented responsibly, and should prevent the use of irresponsible health checks. In addition, the government should help to ensure that people are provided with good quality, comprehensible information that will enable them to make an informed choice about whether or not to undergo a health check. The need for information about the appropriate use of health checks is not restricted to potential participants. Training should also be given to medical professionals to enhance their knowledge of this area, and to teach them how to transfer that knowledge to others. An appropriate information system about the range of health checks on offer would be an important means for increasing people's knowledge of such matters. This would require the active support of the government. Finally, monitoring and enforcement is a government responsibility. With regard to the provision of health checks, the importance of monitoring and enforcement in this area is increasing in step with people's growing freedom to choose whether or not to undergo such checks.

Criteria for responsible screening through health checks

An internationally endorsed framework for responsible screening (often interpreted as population screening) has been in existence for many years. One of its major pillars is that the usefulness of detecting a given disease (or its associated risk factors) must be clearly established, another is that the benefits involved must outweigh the drawbacks. In addition, the test methods involved must be both valid and reliable. Participation must be both voluntary and based

on reliable information. Finally, this screening must be responsible, in terms of the use it makes of public and collective health service resources.

The Committee has determined that this framework, along with the responsible screening criteria derived from it, is still appropriate (albeit with some specific adjustments). This applies not only to collective screening in a programmatic context, such as national population screening, but also to individual health checks. Yet there is a distinction to be made here, in that collective screening must involve health gains at population level, while health gains are not necessarily a precondition for individual health checks. For an individual, the results obtained may be of use purely as information or they may be valuable in terms of reassurance. Also, cost-effectiveness is not a prime concern for the individual. Nevertheless, the follow-up costs of health checks and potential waiting lists may have a substantial social impact on the general public.

Legislation and guidelines

The criteria for responsible screening have, to some extent, been enacted in existing quality-based regulatory frameworks, though it is not always clear whether or not these apply to health checks. Moreover, enforcement options in this area are limited. This is because some healthcheck providers are not subject to medical disciplinary law, while enforcement (under the Care Institutions Quality Act) is restricted to the Netherlands.

In addition to general rules, there are some specific rules that apply to screening. For instance, the In Vitro Diagnostic Medical Devices Decree (IVD) imposes conditions on self-testing kits for HIV, tumour markers and hereditary diseases. In addition, the Special Medical Procedures Act (WBMV) could be used to regulate health checks by means of prohibitions or permits, provided that there are compelling arguments to do so (in terms of cost, quality and efficiency). The Population Screening Act (WBO) applies to screening that uses ionising radiation, concerning cancer or concerning serious diseases or abnormalities for which no prevention or treatment exists. The unsolicited provision of health checks that fall into one of these categories is subject to a mandatory permit. As a result, some health checks are regulated more strictly than others. In fact, this group has now been wholly excluded from considerations regarding the need for safeguards.

The recently introduced health check guideline (PMO) is a multidisciplinary guideline consisting of quality requirements derived from the criteria for responsible screening. The guideline is linked to an evaluation system consisting of three major components. Health checks scoring at least 55 percent of the available points for each component are awarded a pass mark. Yet a pass mark is no guarantee that a given health check is actually responsible. Nor is there any requirement to certify a health check provision according to the scoring system. Both commercial and regular health care providers have intimated that they are not prepared to conform to the guideline. While seeing it as a step in the right direction, the Committee has determined that the guideline is not yet adequate to the task of regulating health checks.

The Committee concludes that a responsible provision of health checks is insufficiently guaranteed by the current legal framework.

Scale of increasing protection

The current WBO and the IVD Decree only partially address the complexities of screening through health checks and the necessity to protect people against the risks involved. According to the Committee, the best approach is to describe this issue in general terms. The Committee identified the following seven conditions where, in general, extra protection is required.

Table In general, extra protection in connection with a given health check is required if

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- 1 It is untargeted or broadly focused on a wide range of abnormalities, and where there is a lack of knowledge for example about clinical sensitivity and specificity
 - 2 There is a complex follow-up process, involving (combinations of) follow-up diagnostics, therapy, aftercare and counselling
 - 3 There is a risk of a disproportionate invasion of privacy
 - 4 The target group also includes children and the legally incompetent
 - 5 Is insufficiently proportional to the health problem involved (e.g. too extensive or invasive) or if there are clearly better or less harmful alternatives
 - 6 It might involve major societal effects, such as follow-up costs and/or displacement effects
 - 7 It is focused (directly or indirectly) on severe diseases or abnormalities for which no prevention or treatment exists
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In general, any of these conditions calls for additional protection, in the form of general or additional more restrictive measures. One example of a general measure is the ALARA principle that applies to the use of ionising radiation (As Low As Reasonably Achievable, or always try to find the lowest effective dose). If general measures offer inadequate protection, additional specific measures can

be taken. For instance, by requiring that certain tests can only be performed based on a medical indication, and then only by certified healthcare professionals. Another such measure could be a ban on advertising for a specific health check. Thus a gradually increasing scale of restrictive measures is created.

According to the Committee, to protect people against the most risky health checks, restrictive measures, such as mandatory permits, are still required. The Committee reasons that mandatory permits should be retained for health checks that are focused (directly or indirectly) on severe diseases or abnormalities for which no prevention or treatment exists. In such cases, the drawbacks involved (in terms of psychosocial stress) will probably significantly outweigh the potential (but uncertain) benefits of possible courses of action or information. Mandatory permits should also remain an option for other risky health checks, if alternative measures cannot provide sufficient protection. The use of mandatory permits requires a legal basis, as currently provided for in the WBO.

Independent national screening committee

Which protective measures are needed, and when, to stimulate the appropriate use of health checks, is a complex issue. The Committee recommends that, in this matter, the Minister should be advised by an independent national screening committee. The Health Council's Committee on Population Screening already advises the Minister about screening in general, the usefulness of collective screening (such as programmatic population based screening) and health checks that are subject to a permit in accordance with the WBO. With the introduction of more freedom of choice, the advisory process needs to be expanded to include advice on:

- usefulness and necessity for (additional) protection measures, subject to the conditions described in Table 1, against the drawbacks and risks of specific health checks*
- the evaluation of a particular health check from a specific provider, and whether this particular provision meets the criteria for responsible screening (and, possibly, whether a quality mark is required)**
- the validation process of the health check guideline
- supervision and enforcement

* Inasmuch as this does not concern health checks subject to mandatory permits as provided for in the WBO.

** Inasmuch as this is not subject to the use of mandatory permits as provided for in the WBO.

- content and management of an information system on health checks, for consumers and healthcare professionals
- requirements for the continuing education of professionals and possibly providers and about educating members of the public
- new developments
- research into health checks and research priorities.

Total body scan

Subject to what conditions might total body scans be permitted in the Netherlands? Whether or not total body scans can have benefits is questionable. There is little or no prospect of health gains. However, individuals may be seeking reassurance and may consider this sufficient reason to undergo a total body scan. The risks involved are quite real: it is quite likely that follow-up testing will be involved (if potentially relevant abnormalities are found), subjects may be unsure how to proceed if certain disorders (or associated risk factors) are discovered, while false negative results can lead to unwarranted reassurance. If total body scans become commonplace, which is quite likely, if health insurers decide to include health checks in their supplemental insurance policies, this may undermine important principles such as justice and solidarity in our healthcare system. This is mainly due to the fact that those who cannot afford these scans or who do not wish to undergo them are faced with rising healthcare costs, and maybe also waiting lists, resulting from follow-up testing and treatment.

There is a significant probability that a total body scan will (directly or indirectly) reveal severe diseases or abnormalities for which no prevention or treatment exists. Accordingly, the Committee finds that mandatory permits should be retained in such cases. Specific providers would then have to prove that their (specific) provision of a total body scan meets the conditions for responsible screening. As indicated above, in specific cases, a national screening committee could advise on whether or not a permit is justified. It is impossible to determine, in advance, whether a positive advice might be given regarding the issuing of such a permit for provision of a total body scan (that depends, to some extent, on the specifics of the application in question). However, this would seem to be rather unlikely.

