

# Responsible use of apps for public health

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## Executive summary

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Health Council of the Netherlands



The number of mobile health applications (apps) is rapidly increasing. If apps are to be used for public health purposes, the government will need to ensure that they can be used safely, for example, by guaranteeing the protection of users' privacy. The Minister has asked the Health Council to advise on a framework with criteria to assess how the government can responsibly use health apps for screening purposes. The Council's temporary Committee on Health App Criteria has addressed this question.

First and foremost, the justification for the use of an app by the government to identify (risk factors or a predisposition for) a particular disease in individuals, depends on whether public health intervention is justified at all. There are various assessment frameworks that can be used to determine whether the benefits of a public health intervention outweigh the risks

and burdens. For population screening, for example, the criteria for responsible screening of Wilson and Jungner and of the World Health Organization (WHO) apply. The intervention must, for instance, result in substantial health benefits while burdens and harms for individual participants should be minimised. Population screening with an app will need to adhere to the same criteria as population screening using 'classic' detection methods, such as a mammogram for breast cancer screening.

In this advisory report, the Committee also addresses the use of apps for other areas of disease prevention, namely infectious disease control. Here, collective health benefit needs to be weighed against the burdens involved for individuals. Measures used for infectious disease control can affect individuals' rights and interests, without them directly benefiting from these measures. Existing criteria for public

health interventions can be used to determine whether the collective benefits outweigh the individual burdens and harms. These criteria include effectiveness, fairness, necessity and proportionality.

The Committee finds that responsible use of apps for disease prevention can be assessed against two existing frameworks for public health interventions. Depending on the overall goal of the intervention, use of the app can be assessed against the Wilson and Jungner criteria (for population screening) or against criteria of ethics frameworks for public health (for infectious disease control). These frameworks also set criteria for the methods used to detect or prevent disease. For screening apps, these criteria require further specification as apps may entail specific challenges that set them apart from more traditional detection methods.



Apps differ from more traditional detection methods in that it can be difficult for users to grasp the underlying technology due to its complexity. This makes it more difficult to assess the effectiveness of apps and to adequately inform participants about how such apps work, while it also means that not everyone may be able to use them. And with the large amounts of data that apps can store, there is a risk of misuse of abuse of personal data, especially when apps are, over time, used for other purposes. To minimise the risks involved with the use of screening apps, the Committee has specified a number of criteria within the existing frameworks:

- Validity and effectiveness.
- Protection of privacy.
- Accessibility and fairness.
- Informed consent.

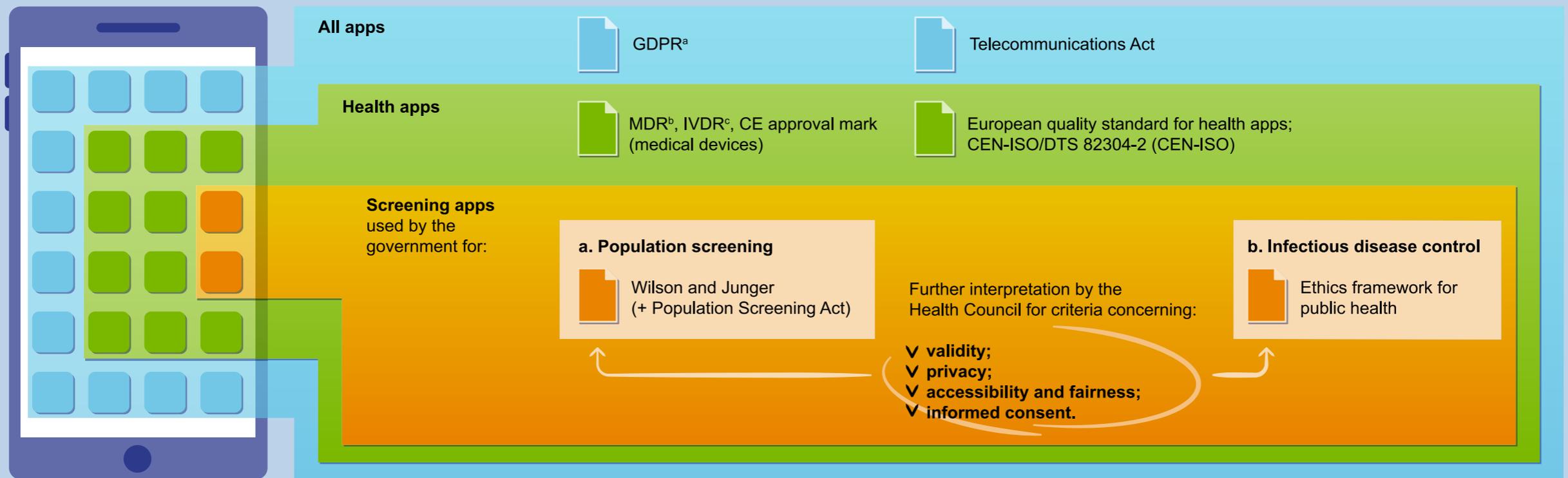
The Committee recommends that these issues be addressed in the early stages of development. Such an ethics by design approach helps to maximise the benefits of screening apps, while minimising unintended negative consequences and protecting people's fundamental rights and interests. For example, the technology must ensure that only personal data that is necessary for the predetermined processing purposes is used (privacy by design). This helps to prevent misuse of personal data.

In addition to the ethics frameworks for public health – and the Committee's more detailed interpretation of some of their criteria in this advisory report – screening apps are also subject to (specific) legal requirements. Apps in general have to comply with data protection legislation (GDPR) and the Telecommunications Act. If the screening app qualifies as a medical device, it must also comply with national and

European Union legislation on medical devices, as well as the corresponding requirements with regard to CE marking and post-market surveillance. It is also advisable to address legal requirements early on in the development phase, taking future use and future obligations into account.



Ethical and legal requirements, criteria and considerations relevant to the use of screening apps for public health purposes.



<sup>a</sup> General Data Protection Regulation    <sup>b</sup> Medical Device Regulation    <sup>c</sup> In-vitro Diagnostics Regulation

Figure 1 Overview of ethical and legal requirements, criteria and considerations relevant to the use of screening apps for public health purposes.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

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