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## Executive summary

Health Council of the Netherlands. Population Screening Act: Rotterdam Study expanded to include liver and skin screening. The Hague: Health Council of the Netherlands, 2011; publication no. 2011/30.

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In this advisory report, the Committee on the Population Screening Act discusses the assessment of an application for authorisation submitted by the Erasmus Medical Centre in Rotterdam. The application concerns two sub-studies within the Erasmus Rotterdam Health Study (ERGO, also called ‘Rotterdam Study’): one related to liver disorders and the other related to skin conditions. The Minister of Health, Welfare and Sport requested an advisory report from the Health Council of the Netherlands within the scope of the Population Screening Act.

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### Background

The Rotterdam Study is a long-term epidemiological population study aimed at accumulating knowledge about the health of and the risk factors for disease among the elderly.<sup>1</sup> The study has already generated many significant results.<sup>2,3</sup> The Rotterdam Study has features of population screening in the sense of the Population Screening Act: men and women aged 55 and older with no complaints or symptoms are screened for risk factors and disorders and they receive medical advice about the screening results. Some parts of the Rotterdam Study also involve population screening for which authorisation is required,<sup>4,5</sup> *e.g.* when the focus is on risk factors for cancer.

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## **Liver diseases**

Though this is not the focus of this sub-study, fatty liver disease might be associated with liver cancer via a number of steps. However, the connection is unclear to such an extent that the Committee cannot regard fatty liver as a risk factor for cancer. What's more, liver cancer is so rare there is no reasonable chance of finding liver cancer among participants in the Rotterdam Study. The Committee concludes that the sub-study on fatty liver disease cannot be regarded as population screening for which authorisation is required and therefore does not need to be tested against the legal criteria.

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## **Skin diseases**

The second sub-study of the Rotterdam Study pertains to skin conditions. The study addresses the prevalence and incidence of and risk factors for skin cancer and other skin conditions, such as psoriasis, eczema and actinic keratosis. Though the Rotterdam Study is not primarily focused on screening for skin cancer, the chance of finding skin cancer is very high. Authorisation is required for population screening for (skin) cancer and this sub-study has therefore been tested against the legal criteria.

In the past, the Committee already ruled that the scientific validity of population screening as a part of primary epidemiological studies, such as the Rotterdam Study, must be assessed in a broad sense. After all, it is not about the efficacy of future population screening.

The Population Screening Act was designed to protect people against population screening that could pose a risk to their health. For this reason, the relationship between benefit and risk and the information provided to the prospective participants in this regard is an extremely important aspect in assessing the legal criteria.

The benefit of the Rotterdam Study is its focus on increasing knowledge. For the participants themselves, there is at most a limited benefit in being screened for (risk factors for) skin cancer. The survival rate for skin cancer is already so favourable (the average five-year survival rate is higher than 90 percent) that population screening can hardly have any positive effect on this. However, there is a health benefit when a tumour is discovered earlier and thus requires a lesser surgical procedure. On the other hand, it is by no means the case that every screen detected tumour would ultimately have led to clinical or cosmetic problems. There is no indication that participants in this study are subjected to signif-

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icant risks: a small skin biopsy usually suffices for the follow-up diagnosis, and surgical procedures almost never lead to complications, let alone serious complications. If premalignant conditions (such as actinic keratosis) are being treated at all, they can be treated with even more limited resources and at even less risk.

With respect to the requirement of 'compliance with legal rules for medical procedures', it is important that prospective participants be properly informed about the limited benefit and minimal risks the study entails for them. The Committee finds this indeed to be the case.

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### **Recommendation**

The Committee sees no reason to refuse authorisation, since the risks are very minimal and both the benefit and risk will be properly communicated to the prospective participants.

The Committee recommends that the Minister of Health, Welfare and Sport grant the applicant authorisation for the sub-study on skin cancer and its preliminary stages for a period of five years. The Committee recommends, that the Minister suggests to register the benefits and risks to enable a report on these issues when a request to extend the authorisation is submitted.