Population Screening Act: risk model studied during screening for colorectal cancer

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Executive summary

Health Council of the Netherlands

The Academic Medical Centre (AMC) in Amsterdam wants to conduct scientific research within the context of the national screening programme for colorectal cancer. The Population Screening Act (WBO) states that the Minister of Health, Welfare and Sport must give permission for any such research. The Committee on Population Screening of the Health Council of the Netherlands has reviewed the permit application against the requirements set by the WBO. It has advised the Minister not to grant the requested permit.

Permit application

The applicant's primary aim is to ascertain whether the national screening programme for colorectal cancer would identify more people with the disease if it were to use a risk model. In the risk model the results of the stool test would not be the only indicator for further tests, as is currently the case in the national screening programme for colorectal cancer. In the risk model, the results of the stool test are combined with information about the incidence of colorectal cancer in the family and smoking (acquired from a questionnaire), and age and gender. Based on this information, the model calculates a risk score to decide whether further tests should be carried out.

The research is randomised: half of the people invited to take part in the population screening programme are offered screening using the risk model. These perform a stool test and complete a supplementary questionnaire (the intervention group). The other half only perform a stool test (the control group). The order of randomisation to decide who will join the intervention group and who the control group, will be determined before the invitations are sent (pre-randomisation).

The stool samples are tested for the amount of blood they contain. If this is at or above a certain level (the cut-off value), the person is referred for further tests: a colonoscopy. For the study a lower cut-off value than the regular cut-off for the national screening programme is proposed. This lower cut-off value means that participants will be referred for a colonoscopy with a lower concentration of blood in their stool than the value used in the national screening programme. People in the intervention group are also referred on the basis of the risk score in conjunction with the concentration of blood in their stool.

Review against WBO requirements

The risk model concerned makes an estimate of the additional returns, which is needed to estimate the required sample size. The study proposal is based on results of a risk model published previously, developed for a different population. The applicant deviates from the previously published model on several points. In addition, certain points in the application are inconsistent and unclear. The Committee was unable to ascertain whether the research design and the sample size have a solid scientific basis.

The Committee recognises the societal relevance of scientific research into risk profiling. However, it objects to the fact that in the proposed research, the control group would not be given the regular screening, but would

(similar to the intervention group) be subject to a lower cut-off value than in the current screening programme. The research increases the risk for all participants. Using a lower cut-off value would increase the chance of being referred for a colonoscopy, which is a demanding examination with a slight risk of complications. In other words, more participants would run the risk of being referred for an unnecessary colonoscopy. This chance is relatively high for participants in the intervention group with a low risk score, and for participants in the control group with a concentration of blood in their faeces below the cut-off value used in the national screening programme. It is the Committee's opinion that the risks for participants are disproportionate to the benefits of the research.

Advice

The Committee has been unable to assess the scientific validity of the research in the application. In addition, the Committee does not consider that the proposed research satisfies the legal requirement stating that the expected benefits must clearly outweigh the risks to participants. The Committee therefore advises not to grant a license for the proposed research application.

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