

PHE's response to the Inter99 trial and NHS Health Check

Inter99 background

In an editorial in the British Medical Journal in June 2014, the Nordic Cochrane Centre said that doctors should not offer health checks to patients, governments should refrain from introducing them, and current programmes, such as the one in the UK, should be abandoned. This editorial accompanied the publication of the Inter99 study.

Inter99 was a randomised trial in Copenhagen that examined the effect of assessing risk factors for ischaemic heart disease (IHD) and providing individuals with repeated lifestyle counselling on their admission to hospitals. It also reviewed deaths caused by IHD at ten years in this cohort.

The main outcomes of interest to the researchers were hospital admissions or deaths caused by IHD. Secondary outcomes included hospital visits and deaths from stroke, combined events (IHD, stroke or both) and total mortality.

The intervention

The study involved assessing IHD risk factors and classifying an individual's risk. Following this, each person had a personal lifestyle counselling session lasting from 15 to 45 minutes. Six sessions of group-based counselling, taken over four to six months, were also offered depending on people's motivation and risk factors. High-risk participants were invited for a repeat assessment and counselling at year one and year three.

The Inter99 design, analysis and limitations

The study randomly allocated 11,708 people to the intervention group and 48,258 to the control group. It also applied an intention-to-treat analysis.

Participants with the top 20% of IHD risk within age-sex specific groups were put into the intervention group. This method will have produced an overall intervention group at moderate risk of IHD. For example, it would have selected women and younger people who were at high risk for their age and sex but not at high absolute risk. This design could have diluted the reported treatment effect.

If they met the unhealthy lifestyle criteria, participants were invited to attend lifestyle counselling. This suggests participants were not blind to their treatment, which could have introduced bias. The authors do not state whether professionals were blind to the allocation of patients.

In the intervention group 52% (6091) attended the initial screening, 37% (4250) received individual lifestyle counselling and 29% (3352) were offered group-based

counselling. There is no information on attendance of these sessions. The low uptake among the intervention group may also have diluted the treatment effect.

The study was designed to look at hospital admissions and deaths from IHD after ten years, but given that it takes time for the symptoms of, or death from, IHD to occur it may be that ten years was not long enough.

Inter99's findings, conclusions and limitations

After adjusting for age and sex, the study found that the hazard ratio in the intervention group was not statistically significantly different from the control group, suggesting the intervention had no effect.

It concluded that screening and low-intensity lifestyle counselling for those at high risk of IHD did not appear to achieve a significant population-level effect on IHD rates after ten years.

The study did not report information on the lifestyle changes or changes in risk factor profiles in either group.

PHE's view of Inter99

After appraising this research, PHE published its [view](#) on the inter99 trial in a position statement from the Expert Scientific and Clinical Advisory Panel (ESCAP) on 20 June 2014.

While the Inter 99 trial adds to the evidence base, the extent to which its findings can be directly applied to the NHS Health Check is debatable. This is because the study uses a different age group, the Danish population has a lower CHD risk profile than the UK population, and the type, intensity and duration of the intervention is not comparable.

PHE welcomes the addition of good quality research to this field, but it is important to recognise that this is a single study. PHE and ESCAP will continue to review evidence as it emerges, and will also consider whether there is enough evidence to consider making changes to the NHS Health Check programme.

PHE's view on the evidence

PHE summarised the evidence to date in '[NHS Health Check: our approach to the evidence base](#)', a joint paper from Professor Kevin Fenton, Professor John Newton, Councillor Zoe Patrick (LGA), Professor Sir Mike Richards (NHS England) and Professor Mike Kelly (NICE). Published in July 2013, the paper also made the case for future research, including collecting and evaluating further data.

In the paper we openly acknowledge that the programme is not supported by direct randomised controlled trial evidence. Nonetheless, there is an urgent need to tackle the growing burden of disease associated with lifestyle behaviours and choices.

Individual elements of the NHS Health Checks follow well-recognised and evidenced clinical pathways approved by NICE.

Since then PHE has:

- worked with partners to set up a research and academic symposium to explore the priority research areas
- developed a paper on research and evaluation priorities, which is due to be published at the end of 2014
- begun work to refresh the 2008 economic modelling, updating the assumptions in the light of new data and experience
- established ESCAP, which reviews emerging evidence and promotes future research (it also promotes the development and evaluation of NHS Health Check, and reviews and provides advice on proposals for changing the programme)

PHE is also clear that if evidence demonstrates the programme is not meeting its set objectives, is causing significant harm, or fails to demonstrate cost effectiveness, we would take action to rectify and improve it. If these issues are insurmountable, PHE would recommend to DH and ministers a future direction for the programme.

Monitoring and evaluating NHS Health Check

PHE is producing a first-ever paper on research priorities for the NHS Health Check programme. This will propose research priorities for the NHS Health Check programme, supporting greater understanding of the impact of the programme and how its benefits for public health can be maximised. Around 100 academic researchers, local authority commissioners and clinicians took part in a symposium in May 2014 to shape the content and direction of the research priorities. The draft will be published for consultation towards the end of 2014 and finalised in the New Year.

PHE has a duty to be a good steward of the public's trust and resources, and rigorous research and evaluation is at the heart of this. We have been clear about the need for research and evaluation to ensure that the NHS Health Check benefits population health, reduces health inequalities, and is cost-effective.