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Inter99 trial: a statement from the NHS Health Check Expert Scientific and Clinical Advisory Panel.

The BMJ published a paper on 9 June on the Inter99 trial. This Danish randomised trial examined the effect that systematic screening for risk factors, followed by repeated lifestyle counselling, has on the ten-year risk of ischaemic heart disease (IHD) development.

Individual research studies such as this provide a valuable contribution to the emerging evidence base. It is important to consider the methodological strength of research findings and their relevance to the delivery of the NHS Health Check programme and other similar schemes. This is why the NHS Health Check Expert Scientific and Clinical Advisory Panel (ESCAP) has rapidly appraised this study.

We are keen to understand the implications for the NHS Health Checks programme and look forward to further discussion on its findings. In the meantime, based on comments from our members, we are publishing this statement in case it helps others appraise the study.

The study was based on a reasonably large sample size and a randomised controlled methodology, including “intention to treat” analysis. This and its use of IHD events as the outcome make it a methodologically strong contribution to a growing area of research. However, only 52% of those invited attended the initial assessment and of those just 37% received the initial lifestyle advice. It is not clear how many went on to receive the full intervention and no sub group analyses were conducted.

In relation to the generalisability of the findings to the NHS Health Check programme, there are important differences in the age profile (30- 60 years) of the Danish population participating in the study compared to the NHS Health Check programme (40-74 years). The underlying cardiovascular disease risk distribution in the Danish study population may also be substantially different (less severe) compared to that reported in the UK. The Archimedes model[1] suggests that even within the same age range the Danish population tends to have a healthier risk profile. The model would also suggest that ten years may not have been enough time for any difference in rate of IHD events to manifest.[2]

The comparability between the study intervention and NHS Health Check risk management approach should also be considered. While the NHS Health Check includes lifestyle interventions, their intensity and duration may not be comparable to those used in the Danish study, although this is hard to assess as interventions vary around the country. Furthermore, primary care management is a key element of the

NHS Health Check programme, a factor that was not included in this study. In general the NHS Health Check is intended to be part of a much wider range of interventions, some at individual level, some at community level, and these other interventions were of course absent from the Inter 99 trial, which was conducted in a research setting.

One of the striking features of the Inter99 trial is that the people who received the intervention did apparently achieve meaningful changes in risk factors, and presumably did therefore benefit (or will do so in future). Yet no population level impact on outcome was seen. This raises the question whether the objective of such programmes should be of individual benefit or population benefit. This trial was set up to measure population benefit, which is a demanding objective for such an intervention, especially in a population that has a low risk overall. It could be said that a more achievable and efficient objective of the NHS Health Check programme would be to identify high-risk cases in order to manage down cardiovascular risk in those individuals. This is something that ESCAP will consider as part the programmes review process.

In summary, the Inter99 study did not appear to achieve a significant population level effect on heart disease rates after ten years by undertaking screening and then providing low-intensity lifestyle counselling to high-risk individuals (within a population at relatively low overall risk).

This experience highlights many of the challenges faced by programmes that attempt population-based interventions, including the NHS Health Check, even though there is evidence to support the effectiveness of the relevant interventions in appropriate individuals. Challenges include the difficulty of achieving high enough intervention response rates, delivering effective interventions, and that the characteristics of people engaging with the programme will determine the nature of the overall population impact, especially in relation to inequalities.

This paper therefore provides a strong contribution to the developing evidence base in this field. ESCAP will continue to review emerging evidence, and will draw on this and other studies to inform its recommendations on delivering the NHS Health Check programme. PHE's forthcoming NHS Health Check research and evaluation strategy will play an important role in supporting the further development of a relevant evidence base.

We hope these brief comments are helpful to others interested in the programme.

[1] Schuetz,C.A et al. (2013) A standardized vascular disease health check in Europe: A cost-effectiveness analysis. www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0066454

[2] Li Li G, et al. (2014) Reduction in cardiovascular and all-cause mortality following lifestyle intervention in persons with impaired glucose tolerane: 23-year follow-up of the Da Qing Diabetes Prevention Study. *The lancet Diabetes & endocrinology*. 2(6) 474-480