Author’s response to reviews

Title: Should heart age calculators be used alongside absolute cardiovascular disease risk assessment?

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Author’s response to reviews:

Dear Dr Kengne,

Thank you for considering our revised manuscript BCAR-D-17-00569: Should heart age calculators be used alongside absolute cardiovascular disease risk assessment?

We thank the reviewers for their helpful and supportive comments. We have responded to the issues that required clarification, and have also addressed the editorial requirements as detailed on the following page. The main changes are:

• Clearer explanation of the primary focus on absolute risk in international guidelines throughout the manuscript, in addition to the existing information about how they have incorporated heart age into this

• Explaining the role of decision aids for risk communication and both lifestyle and medication interventions, using some additional examples that present multiple intervention options (not just statins)

• Clarifying aim 2 and how this is addressed in the paper

We hope the revised manuscript is now suitable for publication in your journal.
RESPONSE TO REVIEWERS

Sandra Ofori (Reviewer 1):

1. Overall well written and thought provoking article. "Heart age" is a concept designed to communicate risk especially relevant to groups who by virtue of age and gender, will have low absolute short term risk but their constellation of risk factors put them at high lifetime risk. The authors are right to note that heart age is not appropriate to use as a guide to medication prescription and would naturally differ when different 'calculators' are used. This may cause confusion when several calculators are used for the same patient.

Thank you for your positive response and highlighting the key issues that the paper is intended to address.

2. However, the basis for this article seems to be that heart age is, or can be used to drive medication prescription and that this is supported by guidelines. The JBS3 and NHS guidelines do not advocate for the use of heart age to guide prescription. They clearly state that in cases where lifestyle changes are not enough to modify risk factors, medication MAY be needed. Furthermore, even absolute risk scores do not reflect a particular individual's actual risk and the whole concept of CVD prevention will be lost on the individual, if their risk is not appreciated by them. The JBS3 heart age calculator presents pictoral charts for interval (5, 10 year etc) outcomes with or without intervention (which could be only lifestyle intervention) which is geared towards enhancing risk communication.

We agree that international guidelines state that an absolute risk calculation should be used to guide prescription, and have now made this clearer in the manuscript to address the points of Reviewers 1 and 2. We aim to make the argument that the use of heart age “alongside” absolute risk assessment in these guidelines is not clearly separated from medication recommendations, even with the use of terms like “may” which we have carefully quoted in the paper. The examples we provide are intended to show how these communication tools can appear to advocate medication on the basis of older heart age even when the absolute risk is low, which is an important issue to be clear on. However to address your concern, we have revised the wording throughout the manuscript to more clearly explain the focus of the guidelines on absolute risk assessment, as follows:

Abstract: While most heart age calculators are promoted as a communication tool for lifestyle change, they may also be used to justify medication when clinical guidelines advocate their use alongside absolute risk assessment.
Page 3: This is in contrast to guidelines advocating the use of heart age alongside absolute risk assessment for medication decision making.

Page 6: This is increasingly likely as more heart age assessment methods are developed and implemented alongside medication guidelines based on absolute risk.3,5,11 There are now multiple heart age calculators linked to clinical practice guidelines and available to the public, conveying conflicting messages about risk and medication. It is essential that doctors and patients understand the assumptions behind these heart age calculators and how they relate to absolute risk-based medication guidelines.

Page 8: Users are informed that they may need medication based on older heart age, even if their 10-year absolute risk is low.

Table 1 + Page 8-9: The NHS calculator suggests that both cholesterol and blood pressure medication may be needed, even though the absolute risk is low in both cases.... The NHS website also says that cholesterol medication may be needed despite being well under the absolute risk medication threshold of 10%.

Page 9: However, while JBS3 guidelines focus on absolute risk assessment, they also recommend that medication should be considered for people with low absolute risk but older heart age than current age.

3. In the last section of the article, "what can we use instead of heart age", the statin choice decision aid is recommended instead of heart age. The two address different levels of risk communication and should not be seen as alternatives but rather complementary depending on what the intention is. This statin decision aid is useful when the decision to start satin is already being considered with the patient and the patient needs to 'see' what how their risk might change with no, standard or high dose satin.

We agree that this particular example is focused on the next step from risk assessment after statins have been offered/considered, so have now clarified that shared decision making based on absolute risks and benefits should be used for all intervention decisions including lifestyle. To better illustrate this we have provided an additional reference exploring patient use of a CVD risk calculator that compares lifestyle and medication approaches based on absolute risks and benefits. We have also reworded several sections to include lifestyle as well as medication.

Abstract: Evidence-based decision aids that improve patient understanding of absolute risk should be considered as alternatives to heart age calculators for lifestyle and medication decisions.

Page 11: The risk communication and decision aid literature provides clear directions for alternative absolute risk formats that could be used to explain CVD risk and the benefits of both lifestyle and medication interventions... This should include verbal explanation of the frequency of CVD events for a given absolute risk result, and visual formats showing the risks and benefits of all lifestyle and medication options in absolute terms.38 Recent qualitative research investigating such visual formats demonstrated how patients find absolute risk more meaningful...
when both lifestyle and medication intervention effects can be explored in relation to this (e.g. using the risk calculator at http://chd.bestsciencemedicine.com/calc2.html). There is strong evidence from a Cochrane systematic review of 105 randomised controlled trials that providing this sort of information in the form of a patient decision aid improves patient knowledge, accuracy of risk perception, doctor-patient communication, and decision making that is consistent with individual values and preferences. For example, the Statin Choice decision aid is an evidence-based, effective tool that demonstrates how this can be done (Figure 2), but it could be improved by allowing lifestyle interventions to be compared to medication options.

4. The authors note that "Using heart age to recommend medication is likely to undermine the absolute risk approach for medication decisions". While this is a valid point, they need to clarify that the current guidelines do not recommend using heart age to guide prescription.

We have clarified this throughout the manuscript as outlined in response to point 2.

Jacek Bil, MD, PhD, FESC (Reviewer 2):

5. This is a thought-out article describing the meaning and the accessibility of the heart age calculators as the point for further discussion.

Thank you for your positive response.

6. However, at the end of the paper is should be clearly stated that European(ESC)/American guidelines recommend to use risk scores rather than heart age calculators when making up clinical decisions.

We have explained that heart age is used for lifestyle rather than medication on page 5, but have also revised the final reference to make this clearer as the European guidelines do make a clearer distinction between absolute risk and heart age compared to UK guidelines.

Page 5: In Europe, vascular age for the SCORE model was published in 2010, and a cardiovascular risk age calculator is recommended to communicate the need for lifestyle change to younger adults in 2016 cardiovascular prevention guidelines.

Page 10: The 2016 European guidelines make a clearer distinction between absolute risk for medication and heart age for lifestyle, stating directly: “both risk age and lifetime risk are closer to relative than absolute risk, and none provides an evidence base for drug treatment decisions”.

7. And the second, the quality of figures must be improved.

We have provided the highest resolution versions of the images that are possible given the need to use screenshots of existing websites.
8. The article was well-written, and provided with a comprehensive discussion... the paper is highly recommended to be published without revision.

Thank you for your positive response.

9. There are, however, there is no enough explanation on the second aims of this paper (to summarise research on the effect of communicating heart age). Thus, I suggest it might be better to be included in the article though the paper is highly recommended to be published without revision.

We have revised the explanation of the second aim to match the section heading that addresses this point.

Abstract + Page 3 “2) summarise research investigating whether heart age improves risk communication”

Page 6 “Does heart age improve risk communication?”

-------------------Editorial Policies-------------------

We have added the following section at the end of the manuscript as required:

DECLARATIONS

Ethics approval and consent to participate: N/A

Consent to publish: N/A

Availability of data and materials: N/A

Competing interests: The authors declare they have no competing interests.

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Author contributions: This ideas presented in this article were developed and discussed over several years based on absolute CVD risk and overdiagnosis research within the STEP and Wiser Healthcare Programs. The release of new guidelines in the US and UK, including the JBS3 suggestion that medication could be prescribed based on heart age, prompted this paper to be written. CB is the guarantor of the article and drafted the manuscript based on her PhD investigating CVD risk communication and decision making, including two heart age studies. All
authors contributed to discussion and revision of the paper. KB and LI are clinical epidemiologists with expertise in test evaluation and CVD risk models. JJ and KM are psychology academics with expertise in shared decision making and risk communication. PG and JD are academic GPs with expertise in evidence-based practice and clinical CVD guidelines.

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