

Gateway Reference Number: 05329

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Tuesday 9 June 2016

Dear colleague

**QRISK2 review process**

You may have heard of today's announcement from TPP about the issues with the QRISK2 score calculator integrated into 'SystemOne' (**appendix 1**) for background).

We recognise that the subsequent process to review patient records will add to the workload of busy practices and we wanted to let you know that NHS England, in conjunction with TPP, will be evaluating the implications for practices.

It is estimated that the average SystemOne practice may need to review up to around 100 patients. Many patients will not require a face-to-face review and, for some, a phone call will be sufficient. For some patients, practices will wish to call patients in for reassessment and to discuss their newly calculated cardiovascular risk profile. For patients where a face to face consultation is required, I attach some suggested template letters for you to use if you wish (**appendix 3**).

Advice has been issued from NHS England National Clinical Directors regarding priority groups for clinical review (**appendix 2**). To support the review process, TPP have published a system-wide statins/antihypertensives Review Template on SystemOne. The template is called 'QRISK2 10 Year Risk Score Review' and will support practices in undertaking patient reviews. For non-SystemOne practices, information regarding any patient who has moved from a SystemOne practice who potentially may be affected will be shared through HSCIC.

We also wanted to let you know that TPP has agreed to undertake, over the next month, an in-depth review of their systems. A key objective, as part of that process, will be to identify the likely impact on general practice in responding to this incident and consider any appropriate compensation. We will therefore be working with a number of sample practices to audit the workload impact of this incident in order to feed into that review.

We will share further information regarding the outcome of the review process in

July.

As always we would like to thank you for your continuing hard work and focus on your patients.

Best wishes,

A handwritten signature in blue ink, appearing to read 'David Geddes', with a large, stylized initial 'D'.

Dr David Geddes  
Head of Primary care Commissioning

## **Appendix 1:**

### **QRISK2 Incident**

#### **Background**

The QRISK2 software tool is used to estimate 10 year cardiovascular risk in individuals.

In April 2016 TPP (The providers of the SystmOne IT system) identified code mapping errors with the integrated QRISK2 Calculator, which is used to estimate 10 year cardiovascular risk in individuals. The issue occurred when the QRISK2 calculator on SystmOne was pre-populated with entries from the medical record, or when QRISK2 scores were used to identify patients through Clinical Reporting. As a result, scores given to patients in practices using SystmOne since 2009 may have been inaccurate. If clinicians have cleared the calculator and manually entered the patient data and medical history fields, the score will not have been affected by the code mapping error. These errors in code mapping do not affect use of QRISK2 when used online.

As a safety precaution TPP asked GPs to stop using the QRISK2 Calculator whilst an investigation was carried out. With assistance from HSCIC and MHRA new code mappings have been created and the QRISK2 Calculator within SystmOne has been validated for use.

Following advice from NHS England, TPP have designed Clinical Reports which identify four cohorts of patients who should be prioritised for clinical review. These reports show a newly calculated current risk score for the patient generated by the validated tool.

For non-TPP (SystmOne) practices, information regarding any patient who has moved from a SystmOne practice who potentially may be affected will be shared through HSCIC.

Newly calculated current risk scores will be higher in some patients and lower in others. Some of the increase or decrease may be due to the original code mapping error and some may be due to change in risk factors or treatment with statins since the original score was calculated. Tests suggest that the average gap between the original and newly calculated current scores is relatively small. The main clinical risk for patients arises when the change in score has taken them above or below the threshold at which treatment is usually considered.

TPP's user guidance on SystmOne will help practices to identify patients for call/recall and support reviews.

NHS England National Clinical Directors have given the following recommendations regarding any patient reviews

## Appendix 2: Advice from NHS England National Clinical Directors

Dr Matt Kearney, GP and National Clinical Director for Cardiovascular Disease Prevention

Professor Huon Gray, Cardiologist and National Clinical Director for Heart Disease

### 1. Prioritising reviews of cardiovascular disease (CVD) risk

NICE recommends that statins are offered to people whose 10 year CVD risk score exceeds 10% and in whom lifestyle changes are ineffective or inappropriate. Until 2014 the NICE threshold for statin treatment was higher at 20%. NICE [guidance](https://www.nice.org.uk/guidance/cg127) (2011, nice.org.uk/guidance/cg127) also recommends that people with stage 1 hypertension (systolic blood pressure between 140 and 160 mmHg) in whom the ten-year CVD risk is above 20% should be offered antihypertensive medication. NICE are scheduled to review hypertension guidelines in June 2016.

The reports created for GP practices will identify affected patients in four categories. All patients who have been given a clinically significant erroneous risk score will need to be informed of this, how this has come about, implications for their care and what actions they can take. Some of this can be done opportunistically over time, but some patients will need more timely review, with priority being given to those who are at the greatest risk of clinical consequences. The following would be a reasonable priority order:

1. Patients who are not on statins, whose original QRISK2 score was below 20% and whose newly calculated current QRISK2 score is 20% or higher **and** patients, who are not on statins, whose original QRISK2 score was below 20% and who have a clinical condition for which statins are recommended as they are inherently high cardiovascular risk.
2. Patients who are not on statins, whose original QRISK2 score was below 10% and whose newly calculated current QRISK2 score is between 10% and 20%.
3. Patients who are on statins whose original QRISK2 score is 10% or higher and whose newly calculated current QRISK2 score is less than 10%.
4. Patients with hypertension who are not on antihypertensive medication, whose original QRISK2 score was below 20% and whose newly calculated current QRISK2 score is 20% or higher.

It is important to note that the newly calculated score is derived from most recent rather than historical patient data, and so part of an individual's increase

in risk score might reflect change in age and clinical conditions over the time period. It is the newly calculated current score that should be used to determine the clinical management.

## **2. Using the QRISK2 score**

NICE makes clear in its guidance that all CVD risk assessment tools provide only an estimate of CVD risk, and that interpretation of CVD risk scores should always be informed by clinical judgement. The QRISK2 calculator is a decision aid that helps us communicate risk to patients. It is also important to remember that QRISK2 should not be used to estimate CVD risk in people with established CVD, or in those with type 1 diabetes, chronic kidney disease 3-5, familial hypercholesterolemia and people over the age of 85 – these individuals should be regarded as being at high CVD risk without the need for risk calculation, and be managed accordingly.

## **3. How should we advise our patients?**

The NICE guidance and quality standard on cardiovascular risk are derived from very strong evidence that lifestyle changes and statins are effective in reducing the risk of cardiovascular events and premature death in our patients. Lifestyle changes should be offered first, and behaviour change should be supported. But if that does not significantly lower cholesterol and risk score, patients should be advised to consider treatment with statins because of the strong cardio-protective effect that these drugs offer. People at increased cardiovascular risk who take statins are significantly less likely to have a heart attack or stroke. Modelling developed by NICE to inform its most recent guidance suggested that every year 8,000 deaths, 28,000 heart attacks and 16,000 strokes could be prevented in England through wider use of statins for primary prevention.

Small numbers of your patients may have an original score over 10% and be taking statins, but have a newly calculated current score below 10%. In this situation it will be difficult to know whether they would still be in the high risk category had they not been treated with statins, because their measured cholesterol on statin therapy will obviously be lower than it was pre-statin. This uncertainty should be discussed with the patient so that they can make an informed decision about whether to stay on treatment. A reasonable approach to this would be to advise patients that we do not know what their correct 'untreated' score would be. Together with lifestyle advice, they could opt to continue on statins, or to have a trial off statins. If they choose to stop statins, the CVD risk score could be repeated annually with the option to restart if the risk score rises above 10%.

## **4. What about patients that have left my practice?**

Patients that have moved to another SystemOne general practice will be reviewed by the general practice where they are registered. HSCIC will trace patients who have moved from SystemOne and will share the patient's NHS Number, previous QRISK2 score and newly calculated current score (based on records available to TPP) with the patient's current general practice. This will provide the minimum necessary information required to enable contact tracing.

**For further clinical advice, please contact the NHS England customer contact centre.**

**Telephone:** 0300 311 22 33

**Email:** [england.contactus@nhs.net](mailto:england.contactus@nhs.net)

**Post:** NHS England, PO Box 16738, Redditch, B97 9PT

**British Sign Language (BSL):** If you use BSL, you can talk to us via a video call to a BSL interpreter. Visit [NHS England's BSL Service](#).

Our opening hours are: 8am to 6pm Monday to Friday, except Wednesdays when we open at the later time of 9.30am.

### **Appendix 3: Possible template letters for use in call/recall of patients (for SystmOne and non-SystmOne practices)**

#### **Guidance note in using these templates:**

1. The following is a possible letter template to help in writing out to your patients, should you choose to use it, alongside a personal phone call.
2. The template letter may not be appropriate in all cases and should be considered in addition to a personal phone call. It will also need to be edited and used according to need.
3. In line with the Accessible Information Standard, patients known to have difficulty or to be unable to read a 'standard' version of the letter should be sent the information or contacted via an alternative method which is accessible to them. This would include patients who are blind or have visual loss, and patients with a learning disability. Accessible alternatives may include a larger print version of the letter, sending the letter via email, or telephoning the patient. Further information about the Accessible Information Standard is available at [www.england.nhs.uk/accessibleinfo](http://www.england.nhs.uk/accessibleinfo) and the contact point for queries is [england.nhs.participation@nhs.net](mailto:england.nhs.participation@nhs.net)

#### **Template letter 1: For 'SystmOne' practices**

GP Name  
Practice Address

Patient Name

Patient Address

Dear

In considering our health advice to you, we use a computer tool which, based on information in your medical records, estimates a 'risk score' of having a heart attack or stroke in the next ten years.

Where the computer tool estimates a high risk score, patients are offered lifestyle advice and, if necessary, statin tablets to reduce the risk of having a heart attack or stroke.

We are writing to let you know that due to an error in this computer tool, there is a possibility that the risk score in your medical records may have either been overestimated or underestimated. This may have influenced the advice or treatment that you were given.

The error with the computer tool has now been fixed. We would like to check your recalculated risk score and check that the advice or treatment you have been given is the best possible for you.

In the meantime please be reassured that no urgent action is necessary. It's perfectly safe for you to carry on taking all of your current treatment until we review this with you.

**[AMEND AS APPROPRIATE]**

We would like to invite you to an appointment on **[Enter Date]**/ Please can we ask you to make an appointment at the surgery.

Yours sincerely,

Dr.

**Template letter 2: For non-SystemOne practices**

Patient Name

Patient Address

Dear

In considering our health advice to you, GP practices use a computer tool which, based on information in your medical records, estimates a 'risk score' of having a heart attack or stroke in the next ten years.

Where the computer tool estimates a high risk score, patients are offered lifestyle advice and, if necessary, statin tablets to reduce the risk of having a heart attack or stroke.

We are writing to let you know that there was an error in this computer tool at a previous practice you were registered with. As a result there is a possibility that the risk score in your medical records may have either been overestimated or underestimated. This may have influenced the advice or treatment that you were given to reduce your risk of heart attack or stroke. We would like to arrange an appointment to recalculate your risk score and check that the advice or treatment you have been given is the best possible for you.

OFFICIAL

In the meantime please be reassured that no urgent action is necessary. It's perfectly safe for you to carry on taking all of your current treatment until we review this with you.

**[AMEND AS APPROPRIATE]**

We would like to invite you to an appointment on **[Enter Date]**/ Please can we ask you to make an appointment at the surgery.

Yours sincerely,

Dr.