

## QRISK or Framingham for predicting cardiovascular risk?

QRISK is better on every performance measure, and should be recommended in the UK



ERIC HERZOG/CUSTOM MEDICAL STOCK/SPL

### RESEARCH, p 144

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In the linked study, Collins and Altman assess the performance of the QRISK cardiovascular risk prediction algorithm in a primary care setting in the United Kingdom,<sup>1</sup> and compare QRISK<sup>2,3</sup> with equivalent Framingham algorithms.<sup>4,5</sup>

The QRISK algorithm is based on the largest risk prediction study ever undertaken and highlights a potential use of large scale electronic health record systems.<sup>2,3,6</sup> In just a few years, a small team has linked electronic health records from several million people to produce a cardiovascular risk prediction algorithm that is more accurate and better validated than previous ones. Although prediction algorithms are available for many conditions, most are based on small numbers, are poorly validated, infrequently updated, and not generalisable. Moreover, most prediction algorithms are weak predictors and are not used regularly.

The first QRISK prediction algorithm was generated by retrospectively extracting data on risk factors and subsequent cardiovascular events for almost two million people from the QRESEARCH primary care database of more than 10 million patients covering about 7% of the population of the United Kingdom.<sup>2</sup> It was validated by the developers in another large database,<sup>3</sup> and a year later they published an updated and improved algorithm, QRISK2, which included several additional predictors.<sup>6</sup>

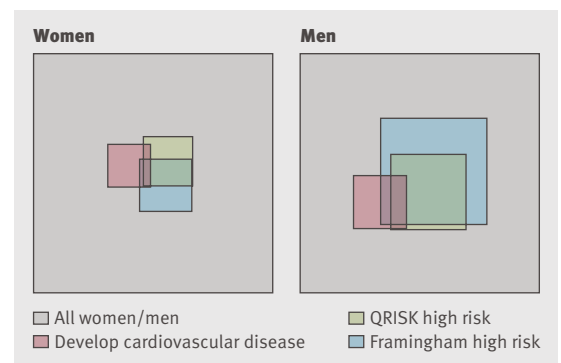
Collins and Altman<sup>1</sup> now provide an independent evaluation of the first (QRISK1) algorithm and compare its performance with three Framingham algorithms.<sup>4,5,7</sup> They conclude that on every performance measure, QRISK1 is better than Framingham. Unfortunately, because of the timing of publications, they were unable to compare QRISK2 with a recently modified version of the Framingham algorithm recommended by the National Institute for Health and Clinical Excellence (NICE) in 2008. This modified Framingham algorithm includes adjustments for family history and ethnic origin.<sup>7</sup> Although not an independent evaluation, Hippisley-Cox and colleagues have now compared their QRISK2 algorithm with the NICE modified Framingham algorithm and again QRISK performs better.<sup>6</sup>

Direct comparisons between QRISK and Framingham are perhaps a little unfair because Framingham algorithms have not been calibrated to the UK population, although this is a relatively easy mathematical

adjustment.<sup>8</sup> However, an algorithm's ability to discriminate between patients who will have an event and those who will not cannot be so easily improved and this is where QRISK has a slight edge on Framingham. More importantly, because QRISK2 performs better than QRISK1, further improvements are likely in future iterations.

But a closer look at the Collins and Altman evaluation provides a sobering message about the current state of cardiovascular risk prediction.<sup>1</sup> Our figure uses scaled rectangles to re-present some of their data, and it illustrates more clearly the modest discrimination performance of both algorithms at recommended treatment thresholds.<sup>9</sup> QRISK would classify one in 10 men in the UK as high risk—that is, having a 10 year cardiovascular risk above the threshold recommended by NICE for treatment with statins.<sup>7</sup> However only 30% of the subsequent cardiovascular events in men occurred in this high risk group. In contrast, the Framingham algorithm would classify about twice as many men in the UK (one in five) as being at high risk, although this larger high risk group does not include twice as many of the men who had a cardiovascular event during follow-up (it included only 50%). Substantially fewer women were identified as high risk (about 4% by QRISK and 5% by Framingham), with surprisingly little overlap between the two high risk groups. These high risk groups included only 18% (QRISK) and 17% (Framingham) of women who subsequently had a cardiovascular event.

Almost 80% of participants in QRISK had some missing risk prediction variables, which suggests that



Proportions of men and women classified as high risk by QRISK and Framingham who had a subsequent cardiovascular event (derived from table 5 in Collins and Altman<sup>1</sup>)

QRISK could be improved given more complete data. Furthermore, it indicates that most UK adults have not had a formal documented cardiovascular risk assessment, as recommended by NICE,<sup>7</sup> and that the quality of cardiovascular risk management in the UK (as elsewhere) is suboptimal.

Although UK general practices using the EMIS electronic health record system will have free access to an integrated QRISK calculator, commercial restrictions on the use of the algorithm in other systems are a concern. Cost may become a barrier to the development of effective electronic decision support using QRISK algorithms. Our experience has taught us that developing and implementing a computerised cardiovascular risk assessment and decision support system is a highly specialised task. Three features are crucial to their success: automatic provision of decision support as part of clinician workflow; provision of recommendations rather than just assessments; and provision of support at the time and location of decision making.<sup>10</sup> We have shown that decision support incorporating these features significantly increases cardiovascular risk assessment,<sup>11</sup> but substantial time, experimentation, and wide collaboration are needed.

A QRISK based algorithm should replace the currently recommended Framingham based algorithm for estimating cardiovascular risk in the UK. With increased use, the quality of data will improve and updated prediction algorithms should be more accurate. However, QRISK is just the first of many continuously updatable prediction algorithms that will become available worldwide as electronic health record systems replace current paper based systems. The planned UK

General Practitioner Extraction Service, for example, should soon be capturing data relevant to risk prediction from most of the population.<sup>12</sup> We believe that freely sharing these algorithms is the best way to facilitate their effective implementation.

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## Reducing pregnancy and risky behaviour in teenagers

Youth development programmes don't always work

### RESEARCH, p 148

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Youth development programmes aimed at reducing pregnancy rates and health risk behaviour in teenagers have received strong support in many countries. Proponents of such programmes claim that they are holistic and can focus on the supports, opportunities, and services needed for success; they can tackle multiple risk behaviours, which are thought to be inter-related; and they can help build protective factors as well as reduce risk factors.

One of the most effective youth development programmes, the Children's Aid Society (CAS) Carrera programme, reduced pregnancy by about a half over three years. Its results have been widely reported,<sup>1</sup> and this has led to the implementation of formally sanctioned CAS Carrera programmes, unsanctioned CAS Carrera-type programmes, and other types of youth development programmes.

In the linked matched comparison study, Wiggins and colleagues evaluated a programme based on the CAS Carrera programme and other youth development pro-

grammes.<sup>2</sup> This programme did not reduce the occurrence of pregnancy, however. Instead, pregnancy was significantly more common in the intervention group than in the matched comparison group (16% v 6%; adjusted odds ratio 3.55, 95% confidence interval 1.32 to 9.50). These results suggest that at best the programme had no effect, and at worst it had a negative effect.

One explanation for this effect lies in the methodological limitations of the study. For example, the lack of randomised assignment and slightly different criteria for selection into the programme group or comparison group may have led to the intervention group being at higher risk. Very low follow-up rates may also have affected results.

It is helpful to consider all four studies of the CAS Carrera or CAS Carrera-type programmes collectively. The first published study was a randomised controlled trial of 268 girls and 216 boys in six sites in New York City. In girls, the programme reduced



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current sexual activity, it increased the combined use of condoms and hormonal contraceptives, and it decreased the reported pregnancy rate (by half) over three years; in boys, the programme had no significant effect on sexual risk behaviour.<sup>3</sup>

That study included 12 sites, but only data from the six New York City sites were reported in the initial publication. The data from the other six sites were reported in a subsequent review of many studies.<sup>4</sup> The other six sites, like the New York sites, participated in a randomised controlled trial. This trial included 457 girls and boys. The results indicate that the programme had no significant effect on current sexual activity or the risk of pregnancy (defined as abstinence or use of contraception) in girls or boys. One possible explanation is that the programme was not implemented as completely as in the New York sites.

The third randomised controlled trial included 372 girls and boys. It tried to replicate the CAS Carrera programme, but without training or sanction from the Children's Aid Society. The programme provided no benefit on any measure of sexual behaviour; furthermore, at 13 months of follow-up, the pregnancy rate was lower in the control group, although this effect dissipated by the final 31 months of follow-up. The unexpected finding at 13 months was attributed to the unusually low rate of pregnancy in the control group during that period. The lack of benefit on any sexual behaviour was attributed to the fact that many members of the control group participated in other kinds of youth serving programmes when they were randomised to the control group and could not participate in the CAS Carrera-type programme. The main conclusion was not that these types of activities did not affect sexual behaviour, but that young people could receive them elsewhere, even in communities that presumably offered few programmes for young people.<sup>5</sup>

What can we learn from the pattern of the results across all four studies? One pattern is clear, consistent, and discouraging—none of the four studies found any positive effects on sexual behaviour in young men. This suggests that even intensive, comprehensive, and long term youth development programmes may have no effect on male sexual behaviour.

In girls, three of the four studies failed to find a significant benefit on current sexual activity or use of contraception and two reported significant increases in pregnancy rates. These results indicate that such programmes are not effective unless implemented fully and properly. Multicomponent programmes like the CAS Carrera programme are difficult to implement, and they may be particularly prone to implementation failure, which would dramatically reduce their effectiveness. Also, this programme requires extensive institutional knowledge and support and may not be as effective when implemented outside of New York City by organisations other than the Children's Aid Society. It should be noted that in the first evaluation of the CAS Carrera programme, Michael Carrera—the charismatic programme founder—and his staff trained all the programme staff and visited them regularly.

As was seen in two of the studies, bringing together teenage girls at high risk of pregnancy might actually increase pregnancy rates, either as a result of being labelled as high risk or being exposed to peers who reinforce risk taking norms, as suggested by Wiggins and colleagues. However, more research is needed in this area.

Even though the CAS Carrera programme is intensive, comprehensive, and long lasting the combined results of the four studies were not encouraging. Studies have also shown that academic remediation and vocational education fail to reduce teenage pregnancy and childbearing.<sup>6-8</sup>

But this does not mean that all youth development approaches are ineffective. For example, programmes may be more effective when implemented by charismatic staff, when they facilitate access to reproductive health services, when the staff connect with the teenage participants, or when the staff give a strong clear message about avoiding unprotected sex. Programmes may be less effective when one or more of these conditions are not met. In addition, different types of youth development programmes, such as service learning programmes, may be effective. Such programmes include intensive voluntary service in the community and organised small group discussions to prepare young people for the service and to debrief them afterwards. Notably, several studies have consistently shown that service learning programmes can have a positive effect on sexual risk behaviour and reported pregnancy rates.<sup>9-12</sup>

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## Treatment of chronic gastro-oesophageal reflux disease

Early results of laparoscopic fundoplication show promise, but need confirmation

### RESEARCH, p 152

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Symptoms of gastro-oesophageal reflux are common—about 25% of the community experience heartburn and 5% have symptoms daily.<sup>1</sup> Proton pump inhibitors are the mainstay of treatment for moderate to severe symptoms because randomised controlled trials (RCTs) show they are the most effective medical treatment.<sup>2</sup> When these drugs are discontinued symptoms often relapse, so most patients take them long term.<sup>3</sup> This is inconvenient for patients and expensive for the health service. Concerns also exist over the long term safety of this treatment—continued acid suppression is associated with increased risk of infective diarrhoea and hip fracture,<sup>4,5</sup> although whether these associations are causal is unclear.

The alternative to long term treatment with proton pump inhibitors is surgery. In the linked study,<sup>6</sup> Epstein and colleagues report the results of a cost effectiveness analysis of a large RCT by Grant and colleagues comparing laparoscopic fundoplication with proton pump inhibitors.<sup>7</sup> The advent of this type of surgery has reduced the morbidity and cost of surgery and made it a viable alternative to drugs.<sup>8</sup> Three earlier RCTs compared laparoscopic antireflux surgery with proton pump inhibitors in a total of 875 patients with gastro-oesophageal reflux, with conflicting results.<sup>9-11</sup> Two RCTs reported that surgery was more effective than proton pump inhibitors in relieving reflux symptoms,<sup>9,10</sup> whereas the largest trial indicated that they had equal efficacy.<sup>10</sup>

Grant and colleagues' pragmatic trial conducted in secondary and tertiary care recruited more than 800 subjects with longer than a 12 month history

of gastro-oesophageal reflux disease, confirmed by endoscopy or 24 hour pH monitoring.<sup>7</sup> Almost half were randomised to receive laparoscopic fundoplication or optimal medical treatment. The primary end point was improvement in the patient reported reflux quality of life score, and at first glance the data seem compelling, with significant improvements in scores in those assigned to surgery, despite more severe symptom scores at baseline, and a reduction in subsequent use of acid suppressants. Perioperative morbidity and conversion rates to open procedure were low, and later complications of surgery were rare. These data suggest that people with gastro-oesophageal reflux disease who need long term acid suppression would benefit from laparoscopic fundoplication.

However, it may be premature to incorporate the results into clinical practice. Although randomisation will have minimised the possibility of confounding factors influencing the results, the nature of the surgical intervention precludes the trial from being double blind. Participants could therefore be biased in their assessment of symptoms, and those who had surgery may have, consciously or unconsciously, exaggerated their symptoms at baseline and minimised symptoms during follow-up.

Interestingly, half way through the trial the data monitoring committee requested that participants be informed of the group that they were randomised to after completing the baseline questionnaire because they were concerned that "this could potentially affect their response." This change would have reduced possible bias at baseline, but not during follow-up. Of course, all trials of surgery for gastro-oesophageal reflux will have this flaw, and this is not a criticism of the investigators, but it means that results based on subjective symptom assessments need to be interpreted with caution. Trials of laparoscopic antireflux surgery understandably focus on subsequent improvement in reflux symptoms, but the procedure can have non-reflux related complications, such as dysphagia and bloating. Current evidence suggests these adverse sequelae are uncommon,<sup>7-11</sup> but an evaluation of patient reported overall quality of life would be the most holistic assessment of the effect of surgery. Grant and colleagues measured this using the EQ-5D and found no significant difference between the two groups, which is consistent with another trial.<sup>10</sup>

Finally, an important consideration is whether surgery is cost effective. Epstein and colleagues extrapolated data from Grant and colleagues' trial over a lifetime using a Markov model.<sup>6</sup> Their results suggested that surgery was likely to be cost effective, but as with most economic modelling studies this was



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dependent on key assumptions. In particular, the base case model assumed that gains in quality adjusted life years would persist for the lifetime of the individual, and that the cost of proton pump inhibitors would stay the same. If both of these assumptions were inaccurate the authors concluded that it would be much more uncertain whether surgery or medical management was more cost effective. But as proton pump inhibitors become generic their price will probably fall dramatically, and RCT data on the long term benefits of surgery are sparse. We therefore need more data on long term benefits before we can be confident that surgery is cost effective. This is consistent with the modelling of another UK trial, which suggested that patients will need to be followed up for eight years before surgery becomes cost effective,<sup>12</sup> and this duration may increase as generic proton pump inhibitors become cheaper.

Laparoscopic antireflux surgery is not for everyone. The fact that only 62% of patients randomised to surgery in this trial underwent the procedure shows that patients need to be selected carefully. Nevertheless, surgery is an important option to consider in patients taking long term proton pump inhibitors. Pragmatic RCTs of this type are difficult to conduct, as the failure to meet the power calculation in the present trial shows. However, initial results are encouraging, and more information will emerge with further follow-up.

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## Heat waves and dehydration in the elderly

Recognising the early warning signs can save lives

The heat wave of 2003 caused an excess mortality of 150% across all age groups, with the largest increase (160-200%) in older people.<sup>1</sup> Excess mortality was high across the whole of western Europe (>50 000 deaths) but highest in big cities such as Paris (1854 deaths).<sup>1</sup> The death rate was particularly high in cities that were unaccustomed to high temperatures, and cities with warmer climates, such as those in southern France, were spared. This death toll was not followed by a subsequent decline in death rate, which can occur when serious environmental stress causes premature mortality in the frailest people.

No universally accepted definition of a heat wave exists. An alarm signal should be given for frail older people when the outdoor temperature exceeds 90°F (32°C) for three days or more, which is the most universally accepted definition of a heat wave. Meteorologists predict that global warming will dramatically increase the number of such periods.

The main causes of death in unexpected warm periods are dehydration, heat related morbidity (heat

stress, heat exhaustion, hyperthermia, heat syncope, and heat stroke), cardiovascular events, renal failure, complications of delirium, and respiratory diseases.<sup>1</sup> Dehydration with or without concurrent electrolyte disturbances in itself is an important cause of death, but it is also an important factor in most other causes of death, including the vicious cycle of thermoregulatory failure. Older people who live in big cities that are not prepared for heat waves or in areas with clear “heat island” effects—in old buildings without insulation or air conditioning, or with a bedroom located directly under the roof that keeps the heat longer than the rest of the atmosphere—have the highest risk of heat related morbidity.<sup>2</sup> Frail older people who lived alone, who had low socioeconomic status, pre-existing chronic diseases, and were taking several drugs—such as diuretics, neuroleptics, benzodiazepines, and non-steroidal anti-inflammatory drugs—had the highest heat related mortality in Italy and France during the 2003 heat wave and in a report from the United States.<sup>3</sup>

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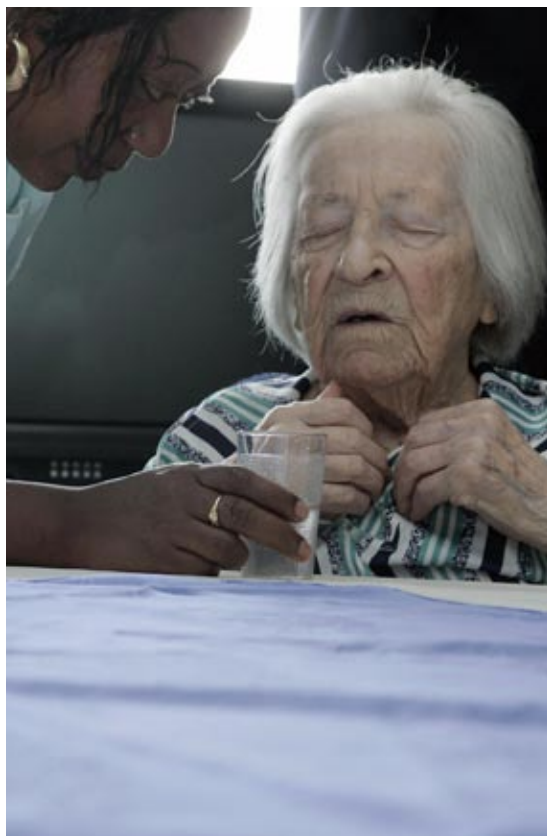
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The key pathophysiological problem is early dehydration. Having less extracellular and intracellular water further jeopardises thermoregulation through decreased production of sweat and a reduced direct loss of skin warmth because dehydrated skin provides increased insulation.

The severity of dehydration depends more on the relative loss than on the absolute loss of total body water—both intracellular and extracellular.<sup>4</sup> The lower a person's body weight and total body water, the sooner the loss of even a small amount of body water will cause symptoms and signs of dehydration. This is why the reduction in total body water, a common sign of ageing, is an intrinsic risk factor for dehydration in elderly people.<sup>5</sup> Thirst and the capacity to conserve salt and water reduce with age and are the most important additional risk factors.<sup>6</sup>

If older adults function independently they fulfil their daily water needs easily through their meals and social drinking.<sup>7</sup> However, a substantial number of older people (up to 25% of people aged 85 and over) drink less than one litre (35 fluid ounces) of fluid a day.<sup>8</sup> The limited capacity of homeostatic mechanisms and the increased dependency on caregivers become important when fluid balance is at risk—for example, in unexpected heat.

Signs of dehydration in the elderly that are easy to recognise include a reduced attention span, lower blood pressure, and dryness of the tongue and mucous membranes.<sup>9</sup> Classic symptoms of dehydration such as reduced skin turgor, increased

thirst, oliguria, and orthostatic hypotension are far less sensitive and specific in older people. Delirium, as always, is an additional warning sign. Serum creatinine is the most sensitive laboratory measure, although body weight is most responsive to changes in hydration.<sup>10</sup> By itself, dehydration is an important indicator of neglect.

Nationally, implementation of preventive measures such as electronic alerting systems, education of populations at risk (to dress lightly, take frequent showers, and avoid alcohol), introduction of reflective paving and roofing systems, and increased planting of urban vegetative cover can reduce heat related mortality.<sup>11</sup> For the individual, recognising frailty, such as in older people who have shown a gradual decline in physical or mental performance during the past year, can help select those who need careful monitoring of fluid balance. This may consist of daily weighing and regular (for example, weekly) measurements of serum sodium and creatinine concentrations. All frail older people should drink two litres of water, milk, or fruit juice a day. In case of weight loss, this should be augmented with fluid equalising the loss of weight in the past 24 hours.<sup>12</sup> Drugs that suppress thirst (such as selective serotonin reuptake inhibitors, angiotensin converting enzyme inhibitors, anti-Parkinson drugs), disturb thermoregulation (such as antipsychotics,  $\beta$  blockers, and drugs with anticholinergic properties), or disturb fluid balance (such as diuretics and lithium) should be reconsidered, temporarily stopped, or their dose reduced.

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