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LETTERS

QRISK VALIDATION AND EVALUATION

QRISK may be less useful

Collins and Altman inappropriately criticise the National Institute for Health and Clinical Excellence (NICE) for not choosing QRISK to predict cardiovascular risk. In doing so, they do not distinguish between assessing individual cardiovascular risk (as used by clinicians) and predicting risk of cardiovascular events in an actively managed population (as used in public health planning). As most tools predicting cardiovascular risk were developed in actively managed populations, they will underestimate the risk that clinicians and patients are initially interested in: the risk if no further treatment

is initiated. This distinction seems to be overlooked in most discussion of cardiovascular risk.

Most doctors would expect to explain the risk to patients were they left untreated. As with several other tools, however, QRISK was derived from a population cohort that may start additional treatments once found to have high rates of risk factors. Hence it is not surprising that it underpredicts cardiovascular risk.

The Framingham study was conducted before the widespread use of effective treatment for cardiovascular risk factors and therefore its equations seem to overpredict cardiovascular risk when assessed in a population with active management of risk factors.

QRISK tried to adjust for baseline antihypertensive treatment, but its investigators admitted that this was a crude measure of blood pressure treatment. Furthermore, it did not adjust for patients who started treatment between baseline and the end of the study.

Although QRISK seems to be more accurate in predicting cardiovascular events in a contemporary UK population, it may be less accurate in communicating risk to patients. For risk communication and individual decisions, cardiovascular risk should be based on study populations that do not receive additional treatment for cardiovascular disease.

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- Collins GS, Altman DG. An independent external validation and evaluation of QRISK cardiovascular risk prediction: a prospective open cohort study. *BMJ* 2009;339:b2584. (7 July.)
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Bespoke cohort studies needed

Despite Collins and Altman's re-analysis of data from the THIN database to validate the QRISK equation for predicting cardiovascular disease,¹ adoption of QRISK in primary care is premature

because key issues about the handling of missing data and the use of social deprivation indices remain unresolved.

Collins and Altman again highlight that complete data were available for just over a quarter of subjects. We appreciate that imputation methods were applied, but we question use of age-sex means of QRESEARCH data for lipid concentrations and blood pressures. This implies that

QRESEARCH data were missing completely at random within age-sex strata—an assumption acknowledged as incorrect when the developers of QRISK revised their equation². It also implies that observed QRESEARCH data reflect age-sex norms in the population—an assumption questioned by the developers' comparison of their data with the health survey for England.³ We call for additional validation using data from bespoke cohort studies in which much greater attention has been paid to completeness of data.

Deprivation indices by their nature quickly become outdated, the Townsend index in particular being based on data from the 2001 census. It should be replaced with variables whose meaning is less context dependent, and which reflect underlying causes of inequalities in cardiovascular disease. For example, subcategorising non-smokers as either "exsmokers" or "never smokers" would perhaps diminish some of the apparent predictive power of the Townsend index (since former smoking is likely to be more common among more deprived communities) and would allow QRISK to be more portable in its future use.

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ASSIGN, QRISK, and validation

We challenge the recent QRISK validation and editorial concluding that QRISK is the cardiovascular risk score for the United Kingdom.¹²

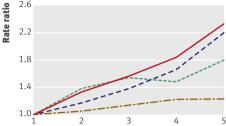
ASSIGN, QRISK's precursor, was launched in Scotland before QRISK appeared.³ Predicting that scores omitting social deprivation (socioeconomic status) as a risk factor could exacerbate social gradients in disease, we developed ASSIGN to include it. ASSIGN was adopted without external validation because it correlated highly with the gold standard Framingham score. Discriminating rather better, even after adjustment for self-testing bias, it removed Framingham's social inequity.

Subsequent to ASSIGN's launch, QRISK authors told us that they were developing their own score. Our offer of collaborative comparison was not accepted, and QRISK coefficients were kept secret after its launch. The initial partisan publication, however, did show that ASSIGN discriminated better than Framingham in the QRESEARCH database where QRISK originated.⁴

We have not seen how QRISK deals with social deprivation in analyses similar to ours—possibly because we have full 10 year follow-up of our cohort. QRESEARCH and the validation THIN database do not. Both these databases are missing 70% of data on lipids, and probably more on family history of cardiovascular

J.





Fifth of social deprivation

Social gradient by deprivation fifth in men for mortality under 75 from coronary heart disease in England and Scotland, and cardiovascular event rates in QRESEARCH and Scottish heart health extended cohort studies

disease. There is a surprisingly flat social gradient in cardiovascular event rates³⁻⁵ and in men at high risk with the Framingham score in QRESEARCH (figure).⁴

ASSIGN and QRISK scores may serve different priorities with different advantages. We welcome debate and collaborative comparisons, but question whether QRISK is the preferred score for the United Kingdom when ASSIGN is already adopted in Scotland (www.assign-score.com).

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 $\label{lem:competing} \textbf{Competing interests:} \ \ \text{The authors instigated the ASSIGN score}.$

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Authors' reply

The Framingham model currently recommended by the National Institute for Health and Clinical Excellence (NICE) to predict cardiovascular risk has stood the test of time. However, it was developed several decades ago from a relatively small cohort

of predominantly white middle class people in the United States. Patient characteristics have since changed (falling blood pressure, increasing obesity, reduced smoking), and health outcomes have improved. Liew and Glasziou point out that some patients in the QRISK derivation and validation cohorts may have started additional treatments once they have been identified as having high risk factors. Obtaining treatment naive population cohorts, such as the Framingham cohort, to develop risk scores is now practically and ethically impossible. Also, while natural history is important, it is not clear that prognosis is best assessed from an untreated population.

Morris and colleagues call for further validation of QRISK on bespoke cohorts, where greater attention to data collection and cleaning will enhance the completeness of data. However, such high quality cohorts, if they exist, will be highly selective and not as representative of the UK population. The Department of Health vascular risk assessment programme is designed to be applied to the whole UK population with emphasis on primary prevention of vascular disease. QRISK was developed and validated in large cohorts of patients from UK general practices.¹⁻³

Morris and colleagues and Tunstall-Pedoe and colleagues mention the low level of completeness of data. The high level of unrecorded values for one component of the QRISK risk score, total serum cholesterol/HDL ratio, dramatically reduced the proportion of people with complete data.

Few risk models have undergone such extensive validation and scrutiny as QRISK on such large cohorts that are truly representative of the target population. By contrast, little attention has been paid to the unexplained and unvalidated inclusion of adjustment factors currently recommended by NICE to adjust the risk for men of South Asian origin and those with a family history of coronary heart disease.

Morris and colleagues also observe that the Townsend score used in QRISK is outdated. Although our role was to provide an independent and objective evaluation of the performance of QRISK, we are aware from the QRESEARCH website (www.gresearch.org) that QRISK is designed to reflect current practice in recording of clinical information. QRISK will be updated to reflect changes and improvements in recording of information and changing patterns of population characteristics, as well as availability of more sophisticated statistical methods. For example, Morris and colleagues question the use of age-sex reference values to replace missing data; a more sophisticated multiple imputation approach was used for QRISK2, the successor of QRISK.4

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Competing interests: None declared.

- Hippisley-Cox J, Coupland C, Vinogradova Y, Robson J, May M, Brindle P. Development and validation of QRISK. a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study. BMJ 2007;335:136.
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NEUROPATHIC PAIN

Management is more than pills

We have one important caveat in relation to Freynhagen and Bennett's review—that evidence based non-pharmacological treatment for neuropathic pain was absent.¹

Several randomised controlled trials show that graded motor imagery reduces pain and disability in chronic complex regional pain syndrome 1 (CRPS1) and phantom limb pain after amputation or brachial plexus avulsion injury.² The number needed to treat for a 50% decrease in pain and a four point drop on a 10 point scale of disability is around 4,³ which compares favourably with any other treatment for chronic CRPS1, including spinal cord stimulation.¹ Cognitive behavioural programmes reduce disability and pain in a range of neuropathic pain states,⁴ and sensory discrimination training reduces pain in chronic phantom limb pain and possibly chronic CRPS1.⁵

These treatments were devised, and continue to be refined for people with chronic neuropathic pain, since the discovery of robust and profound changes within the central nervous system, including the brain. Continuing progress in this field suggests that we can train the brain and reduce pain and disability.

Freynhagen and Bennett state that traditional acupuncture in neuropathic pain is not supported by current evidence but imply support for acupuncture on the basis that it is comparatively harmless. Other comparatively harmless non-pharmacological treatments with level I or II evidence of efficacy were not mentioned. We believe that general practitioners and clinicians should be aware of all the evidence based pharmacological and non-pharmacological treatments available to patients with neuropathic pain, not just the pills.

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OTTAWA RULES, OK?

The myth of complexity

Thompson's comment on Bessen and colleagues' attempt to encourage uptake of the Ottawa ankle rules perpetuates the ubiquitous misuse of the term complex.¹² Referring to the clinical decision tool as complex detracts from the challenges of achieving change in adaptive systems showing "dynamic conservatism."³ The delivery of health care entails people

OTTAWA

Reducing

x rays

RULES: OK?

unnecessary

For-profit or not-for-profit nursing homes?

and procedures operating in systems designed to achieve a range of goals. Sometimes goals and evidence conflict.

In the context described by Bessen and colleagues the intervention does not explain the problems of implementing evidence based practice. The Ottawa ankle rules were informed by evidence that suggests that at a population level lots of x ray films are unnecessary. However, clinicians in accident and emergency departments deal with individual people.

Six year old Tarquin has fallen off his swing and is taken to hospital because he is complaining of a painful ankle. The nurse is sure it is not broken, but Tarquin's mum and dad are not happy about him being sent home without an x ray. Tarquin is sent for x ray, receives the all clear, and he and mum and dad go home happy. The nurse is unlikely to have agonised over the detail of the Ottawa ankle rules, although she attended a recent in-service tutorial and has the new form. She is concurrently expected to get people in and out of the department within target times, avoid re-

presentation of patients, and provide patient centred care. Furthermore, she would rather be safe than sorry—when she trained, evidence based medicine was firmly in favour of radiography to promote patient benefit rather than its minimisation to promote efficiency savings.

Calling comparatively simple interventions complex obscures a fundamental flaw in the evidence based quest for predictability. Better ways are needed to understand the inherent unpredictability of outcome generation.

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Competing interests: None declared.

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Rules are different in diabetes

Mayer describes how clinical prediction rules can avoid unnecessary investigation of the injured ankle and foot, 1 but users of any set

of rules need to know their limitations.

Patients with diabetes and severe distal sensorimotor neuropathy may present with a bruised and swollen foot as a result of a bony injury but remain free from pain and still fully able to weight bear without complaint. Such injuries may have occurred without any clear antecedent history or after apparently trivial trauma.

In this context the absence of pain is no reassurance against there being a bony injury. Walking with ease on a red, hot swollen foot is highly abnormal, and a thorough clinical and radiological assessment is essential. Failure to diagnose such an injury early and put in place appropriate off-weight bearing measures may result in severe deformity and disability.

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Competing interests: None declared.

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UNNECESSARY INTERVENTIONS

If less is more, how much is zero?

If we need less medicine, 1 how much less? Given the accumulating evidence that revascularisation may not add anything to patients' changing their lifestyle, how much angioplasty or coronary artery bypass grafting should be performed? The peer reviewed evidence overwhelmingly suggests that in most stable cases the answer is none.

Why has primary health care failed? Why has Health for All by 2000 been lost to oblivion? Why is prevention a far cry? Why has caring for the sick become all of health care? And, why has the practice of medicine been reduced to maintaining and nurturing preventable and reversible diseases among those who have them, while allowing these diseases to afflict those who don't yet have them?

The answers may not be palatable for a sick care society that has become so addicted to medical breakthroughs that 80% of preventable and reversible lifestyle diseases are treated with lifelong drug treatment. It's high time to bring down the threshold of less medicine, and change the meaning of prevention and primary health care from merely preventing diseases to preventing the adverse effects of lifelong therapeutic dependence.

So how low can the threshold go? Zero?
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Competing interests: None declared.

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Cite this as: BMJ 2009;339:b3500

VALUING HEALTH DIRECTLY

WHO values health directly

The World Health Organization has a pathway to measure and value health.¹

From 2002 to 2004 it asked over 300 000 people across 70 countries to value different health states using a visual analogue scale, supplementing this with studies comparing direct and indirect valuation methods.23 Using this information and guided by burden of disease estimates, the WHO Multi-Country Studies unit collected longitudinal data on self rated and measured health and quality of life assessments with the WHO quality of life instrument and the day reconstruction method alluded to by Dolan and colleagues, 1 as part of its study on global ageing and adult health (SAGE).4 The health states measured are a parsimonious set of domains of functioning that explain over 80% of the variance in health valuations, 5 with the

addition of a measure of subjective satisfaction in different areas of life and a time weighted measure of affective states.

This provides the data needed to assess the dynamic interplay between health and wellbeing over time and to derive the value that people place on their state of health.¹ This needs to be related to the effectiveness of interventions in different groups, including the growing population of older adults worldwide. Older people in all countries value health gains and the interventions that provide that gain. SAGE will provide empirical data on health state valuations, for the first time combining these two approaches to directly examine the determinants of the value that individuals in the general population attach to their health world wide. Paul Kowal scientist kowalp@who.int

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Competing interests: None declared.

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NURSING HOMES

Quality reflects leadership

Whether "not-for-profit" or "for-profit" care homes provide differing outcomes remains fraught with difficulties. 12

Care homes generally are becoming more important in health and care systems. Residential care may have fallen in popularity with improvements in housing and support, but the needs of an increasing number of people with dementia have undermined a simplistic notion of the care home in the same way that specialties replaced the surgical and medical beds of a general hospital in the 1950s.

Bupa's 35 000 care home beds in homes in the United Kingdom, Spain, Australia, and New Zealand show striking variation and diversity of use, healthcare support, and commissioning and regulation. In the UK at least half of the pressure sores observed developed before admission to a care home. Restraint is generally now synonymous with the use of sedative drugs, and prescribing varied threefold between primary

care trusts across over 5000 beds in for-profit and not-for-profit homes.³

Pertinent questions about regulation and commissioning include: Are regulators consistent? Are charitable providers treated the same as commercially driven operators? Is commissioning commensurate with complexity or is it adjusted by provider status?

In reality, most not-for-profit providers of care in the world have to operate on a sound commercial basis to make a surplus for new investment and maintain a sense of value in costs. Investors are unlikely to be attracted to any care provider that was not committed to providing quality care.

Care home quality is a complex blend of commissioning, case-mix, and processes. Somewhere in that may be a factor for profit status, but quality is likely to be a reflection of leadership and commitment.

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Competing interests: None declared.

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More on quality of care

In their systematic review of 82 (mostly US) studies, Comondore and colleagues conclude that on average not-for-profit nursing homes provided better quality of care than for-profit facilities.¹ We recently analysed the factors associated with quality of care (measured as the number of failures of national standards at announced inspections) in residential homes (with and without on-site nursing) in one area of England.²

We distinguished three ownership categories: not-for-profit (housing associations, voluntary, local authority, and NHS providers, 27% of the sample); for-profit corporate businesses (29%); and for-profit small businesses (ownership of one or two homes, 44%). Quality of care was significantly lower in small for-profit businesses. Higher quality of care was significantly associated with corporate for-profit ownership.

These differences in the impact of ownership on performance probably reflect the structure, organisation, and financing of the respective healthcare systems. As small independent care homes in England have struggled in the past decade to meet new national minimum standards, the average size of facilities has risen but is still well below that in the US.³ In

our study, corporate providers charged higher fees, had larger proportions of trained staff, and better quality management.

Consensus on the definition of quality of care needs to be reached with capture of factors such as dignity, privacy, rights, choice, and relationships. Whether staffing ratios and qualifications are an indicator or determinant of quality of care also needs to be clarified. We found that the proportion of care staff trained to NVQ level 2 was not significantly associated with the number of failed standards.

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A/H1N1 FLU

HPA advice on antipyretics

Johnson argues that advice on antipyretics from the Health Protection Agency (HPA) contradicts the guideline on the management of feverish illness in children from the National Institute for Health and Clinical Excellence (NICE).¹

In its full guideline NICE recommends that antipyretic agents should be considered in children with a fever who appear distressed or unwell—reflecting the current practice of many health professionals and parents and carers.

HPA guidance is not at variance with this and simply notes that paracetamol and ibuprofen are indicated for pyrexia and pain. It does not recommend their routine use, but accepts that they have their place in appropriate cases. More importantly, the guidance points out that aspirin should not be used in children under 16 years old and cautions the use of either paracetamol or ibuprofen in certain patient groups.

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Johnson G. HPA advice on antipyretics contradicts NICE guideline. BMJ 2009;339:b3050. (28 July.)

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