Cardiovascular risk prediction: balancing complexity against simple practicality

A significant decline in cardiovascular mortality and morbidity has been achieved with the improvements in detection and prevention programmes for major risk factors [such as smoking, low physical activity levels, obesity, and high blood pressure] related to cardiovascular disease (CVD). However, CVD still remains the leading cause of mortality and disability in the world. Collectively, ischaemic heart disease and stroke were the cause of 12.7 million deaths in 2010, increasing from one in five to one in four deaths worldwide during two decades.

Therefore, prophylaxis strategies are essential for CVD management in terms of both primary and secondary prevention. Given the large body of evidence linking dyslipidaemia, particularly increased LDL cholesterol levels with the CVD development, progression, and prognosis, pharmacological therapy, that is statins, are now the mainstay of CVD prevention.

Established CVD puts patients at high risk of future adverse events and they have to undergo appropriate lifestyle interventions and pharmacological treatments (that is, secondary prevention), but no further CVD risk assessment is required. However, risk prediction in patients without known CVD [that is, primary prevention] and particularly decision making with respect to initiation of statin therapy has largely been challenging.

Substantial evidence has emerged that allows wider use of statins for primary prevention despite the data being less robust compared to its use for secondary prevention. A recent Cochrane systematic review on statins for the primary prevention of CVD, which included 18 randomised clinical trials with a total number of participants of 56,934, found that statins reduced all-cause mortality (odds ratio [OR] = 0.86, 95% confidence interval [CI] = 0.79 to 0.94); combined fatal and non-fatal CVD [relative risk (RR) 0.75, 95% CI = 0.70 to 0.81]; combined fatal and non-fatal coronary events [RR 0.73, 95% CI = 0.67 to 0.80]; combined fatal and non-fatal stroke [RR 0.78, 95% CI = 0.68 to 0.89]; and revascularisation rates [RR 0.62, 95% CI = 0.54 to 0.72]. Of note, the reduction in adverse events appeared to be cost-effective. Also, benefits of treatment outweighed possible hazards caused by statins; indeed, apart from type 2 diabetes mellitus [RR 1.18, 95% CI = 1.01 to 1.39], the risk of other possible complications [for example, cancer, myalgia, rhabdomyolysis, liver enzyme elevations, renal dysfunction, or arthritis] did not differ between patients on statins and those on placebo [overall RR 1.00, 95% CI = 0.97 to 1.03].

These findings are in line with the meta-analyses performed by the Cholesterol Treatment Trialists’ Collaborators which found a reduction of the risk of vascular [RR 0.85, 95% CI = 0.77 to 0.95] and all-cause mortality [RR 0.91, 95% CI = 0.85 to 0.97] per 1.0 mmol/L LDL cholesterol lowering with statins in patients without prior history of vascular disease.

Despite significant difference in drugs used and thresholds defined for statin treatment between the guidelines, the majority advocate a 10-year cardiovascular risk estimation. For example, the American College of Cardiology (ACC)/American Heart Association (AHA) recommend newly-derived pooled cohort equations and a 7.5% cut-off 10-year risk. The European Society of Cardiology/European Atherosclerosis Society guidelines intervention strategy is determined via combination of risk according to SCORE chart and LDL cholesterol level, while the Canadian Cardiovascular Society guidelines use a modified Framingham Risk Score [which is the doubled per cent of the Framingham risk in case of family history of premature CVD] and LDL cholesterol levels. Finally, the National Institute for Health and Care Excellence (NICE) suggests a 10% risk over 10 years based on QRISK2 assessment tool as the threshold for starting preventive treatment with statins.

Thus, an accurate prediction of cardiovascular risk by identification of individuals with high probability of incident CVD seems to be of major importance for primary prevention. Risk underestimation may eventually lead to the omission of high-risk individuals for whom statin therapy is beneficial and vice versa, risk overestimation may result in unnecessary treatment and probability of side effects.

In one interesting meta-analysis, primary prevention [rate ratio 1.52, 95% CI = 1.50 to 1.53] and new statin users [rate ratio 1.46, 95% CI = 1.33 to 1.61] were independent predictors of non-adherence to statin medications. Consistent results were obtained in the UK during the first year of NHS Health Check programme.

Precise risk calculation has become even more important since more ‘aggressive’ treatment thresholds have been proposed [for example, 7.5% for AHA/ACC and 10% for NICE guidelines].

A recent article in the BJGP by Gray et al addresses an important question, by comparing four CVD risk assessment tools: QRISK2, JBJS2 (Joint British Societies), and two types of Framingham risk score, one...
laboratory-based (incorporated total and HDL cholesterol) and another office-based (incorporated body mass index instead of cholesterol levels) in 790 individuals without prior history of CVD or diabetes. Their main findings included higher risk predicted with office-based Framingham risk score and JBS2, and highlighting age as the main driver of cardiovascular risk. Unfortunately no data are available for evaluation of actual event rates against predicted risk.

The fact that among the range of available CVD risk assessment tools, there is a significant variability of results and no perfect one exists is probably not new. All of the risk tools supply clinicians with only approximate estimates of the probability of CVD development.

Performance of different scores depends on a number of factors: largely on definition of CVD — total, both hard events (myocardial infarction, stroke, and coronary heart disease death) and soft events (new angina, transient ischaemic attacks, congestive heart failure, and peripheral vascular disease) or hard events only; study cohorts they were derived from (contemporary or old, observational studies or randomised control trials, outcome definitions, duration of follow-up); quality of calibration of risk score to the target population, and incorporation of risk factors into models as continuous or categorised (or binary) variables. Importantly, with respect to statin treatment initiation no one trial used CVD risk assessment for patients’ enrolment.

The previous NICE guideline allowed choice of CVD risk prediction tool for clinicians, the updated new guideline advocates use of the QRISK2 score only. There are several reasons for this: the QRISK2 score has been derived in the UK from a large general practice database and further validated in several external UK cohorts. In addition it has been subjected to regular update and shown to have the best calibration to CVD event rate in the UK.15

Given complexity of CVD pathogenesis, including genetic predisposition, exposure to different risk factors, and increasing ethnic diversity, nation-specific tools (such as QRISK2 score in England and Wales) are likely to perform the best in terms of CVD risk evaluation allowing informed decision on preventive strategies, particularly lipid lowering with statins. Nonetheless, additional score complexity with an endless list of risk factors (that include biomarkers and genes) would be at the cost of simplicity and practicality for everyday clinical practice. Also, not all risk factors have equal weighting, nor are they yes/no phenomenon (as they represent a continuum of risk). Excessive complexity may also hinder implementation or ‘short cuts’ in use that would be to the detriment of the patient. A balance may ultimately be needed between complexity (with marginal improvement in risk prediction) and simple practicality (which allows better uptake and application). Time will tell.

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THE DOCTOR DRUG
An old but still relevant study by Thomas, conducted in 45 different general practice settings, explored 200 British patients in whom no definite diagnosis could be made. All patients were randomly selected for one of two procedures: either they were given a symptomatic diagnosis and medication, or they were told that no treatment was required as there was no evidence of disease. No differences were found in outcomes with respect to reported symptoms and number of new contacts to the GP within a month.1

Thomas later wrote in the Lancet: ‘The placebo effect in general practice is the power of the doctor alone to make the patient feel better, irrespective of medication. It is one of the most important factors in the consultation, yet generally it is neglected, unrecognized, and untaught. A better appreciation of this power would change doctors’ attitudes to the consultation and would result in the making of less illness, the prescribing of less medication, and a better understanding by the patient of his or her condition.’2

CONTEXT IS THE PLACEBO
More than ever, Thomas’s study and the statement are relevant. New research has documented the therapeutic power of placebo defined as the effect of the meeting between the doctor and the patient, and the context in which the specific treatment is given.3–5 Nevertheless, three major obstacles seem to prevent a more targeted use of the placebo effect in general practice.

The first obstacle is the term ‘placebo’. In basic scientific training, we learn that placebo is inert: a fake pill or something to do with deception. This impact must be eliminated when we study the specific treatment effects. We do not like to be ‘merely’ placebo physicians. Yet, the goal in daily clinical practice of ensuring maximum symptom alleviation is gained as a result of both specific evidence-proven treatment and non-specific context-mediated factors, including the impact of the interpersonal encounter between the doctor and the patient.1 Therefore, it might be better to simply forget the word ‘placebo’ and replace ‘placebo effect’ with ‘context-mediated effect’ when we define this effect or describe the effect of the total care experience encompassing the treatment, for instance, the specific effect of analgesics.4,5

SYMPTOMS AND THE BRAIN
The second obstacle is the lack of clarity and precision with respect to where context should, or should not, be used as a relevant treatment modality. Obviously, we cannot treat a severe infection, a fracture, a cancer, or any other biological failure through context-mediated factors. Let us appreciate the progress in high-tech treatment within modern health care. However, the main focus of most treatment, especially in general practice, is alleviation of symptoms, including symptoms caused by (mechanical) biological failures. But symptoms are complex. They are influenced by culture and personal factors, and appear as the result of conscious and non-conscious emotional and cognitive processing of cerebrally perceived signals. These may be expressed as pain, nausea, tiredness, dizziness, anxiousness, depression, and several other conditions in which cerebral signal processing is an essential part of the expression of the disease. We treat the diseased organ with evidence-based drugs and procedures, but the primary focus is to treat the patient who experiences symptoms caused by a diseased organ. Often, we may even treat symptoms without being able to identify the presence of a specific disease.6 Symptoms are strongly modulated by the patient’s expectations and beliefs, and the clinical context surrounding the specific treatment. Essential components of the total context are the doctor’s attitude, especially his or her communication skills, the doctor-patient relationship, the way the doctor applies therapeutic procedures or rituals, and, ultimately, the doctor’s ability to create trust.3,4

RESEARCH IN SYMPTOM PROCESSING
The third obstacle is a severe lack of translational research in cerebral processes and ways to manipulate these. Over the past 20 years, much empirical research has shown impressive symptom-modulating effects, not only from the placebo pill, but also from the context surrounding the encounter between patient and therapist (including therapists practising complementary and alternative procedures, for example, acupuncture).4,5,7 In addition, new types of scanning technology have allowed us to study the biological processes in the brain intensively during the past 10 years, and these processes have been demonstrated to be strongly influenced by a variety of contextual factors. The biological processes and the variations in the context-mediated effects in the brain have now been scientifically proven.7

For decades, clinicians have known that drugs can influence brain processes. It is now time to realise in clinical practice that placebo, or context, in the modern and broad definition of the concept, may influence brain processes — and thereby also the experienced symptoms — just as much, or possibly even more, than symptom-alleviating drugs. It is also time to realise that doctors may actively modulate the total context surrounding the encounter with the patient. The next step is to realise that ‘nocebo’, the opposite of placebo, understood as anxiousness, mistrust, and lack of relationship or contact, may aggravate symptoms and thus outperform...

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“... symptom alleviation is gained as a result of both specific evidence-proven treatment and non-specific context-mediated factors ...”
... the power of the encounter between doctor and patient should not be ignored.

in part or in total, the effect of, for example, analgesic drugs.8

NOCEBO
The recent development in the field has considerable implications for our understanding of the importance of continuity and patient involvement in the complicated clinical pathways that characterise modern health care. In particular when the aim is also to ensure appropriate management of symptoms and not only to repair a (mechanical) organ failure. The new understanding also has implications for the way we inform patients about possible side effects of drugs and treatment, where nocebo effects may be induced; most people tend to experience more severe symptoms if the clinical encounter or setting fosters mistrust, anxiousness, and lack of continuity.7,9

MEDICAL TRAINING
General practice will be particularly affected by this new understanding. The placebo effect, or the context-mediated effect, also referred to as the ‘doctor drug’, forms a crucial part of daily clinical symptom management in general practice, where the goal of maximum symptom alleviation is based on a combination of randomised controlled trial–documented treatment and the doctor drug. We must use these effects wisely and precisely — and we must train doctors to do so.

The pre- and post-graduate teaching community is currently facing a challenge to convey this message and to train students and young doctors in the use and dosage of these effects. Young doctors should learn about the scientific evidence base of context-mediated effects, including their clinical limitations. We must make doctors aware of the negative associations that are incorrectly attached to placebo.

CLINICAL RESEARCH
The new knowledge about context-modulated symptoms has important implications for all clinical research. The classic randomised controlled trial, where we try to eliminate or neutralise the placebo effect, has severe limitations when it comes to trials for which the outcome measure is perceived symptoms as these are modulated in the brain. The processing of symptoms is influenced by the patient’s daily life and the context in which treatment is given. Experimental effects may be very different from effects in daily life. Context and its effect are a hidden and often uncontrolled part of the intervention, which may cause severe positive or negative bias when we attempt to translate efficacy studies to daily clinical practice. Are producers of Cochrane reviews and so-called evidence-based clinical guidelines fully aware of these limitations in the current research designs, for instance, when procedures are recommended or the effect of antidepressants are discussed?7,10

Efficacy studies cannot always simply be translated into daily clinical practice. The clinical research community in primary care needs to create elegant studies that can identify and document the best ways to precisely use the context-mediated effect in combination with specific treatments in ordinary clinical practice.5,7,10

CONCLUSION
The time is ripe for a stronger promotion of research and training on symptom interpretation and treatment based on our current knowledge about context-mediated symptom modulation. The core message is that we now have a scientific understanding that can explain the observations experienced by doctors since Hippocrates; the power of the encounter between doctor and patient should not be ignored.3,6 We are finally ready to translate Thomas’s wise words into research, teaching and daily clinical general practice.2

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LICENSING EXAMS IN GENERAL PRACTICE

The Royal College of General Practitioners (RCGP) has the responsibility to provide a curriculum and suitable assessments to license doctors to work as GP specialists in the UK. The General Medical Council (GMC), as the Regulator, holds the RCGP to account for the delivery of these functions.

As with all health care, the workload of a GP has become more complex. They are responsible for providing primary care to an ageing population with multimorbidity. Increasingly more of that care is delivered within the community rather than in hospitals. Licensed GPs need to have the knowledge and skills to feel capable of this work and patients have a right to safe and effective care. The MRCGP examination seeks to establish the readiness of candidates to look after patients in unsupervised practice. A recent study has demonstrated the relationship between scores on licensing examinations and patient health outcomes.1

The GP specialty training programme is only 3 years in duration. The MRCGP examination, which must be passed to obtain a certificate of completion of training (CCT), has three components: the applied knowledge test (AKT) attempted from Year 2, the clinical skills assessment (CSA) attempted in Year 3, and workplace-based assessment which runs throughout the entire 3-year programme. The CSA is an assessment of a doctor’s ability to integrate and apply clinical, professional, communication and practical skills appropriate for general practice. It is an objective structured clinical examination (OSCE) style examination of 13 stations.

Using professional role players, the exam assesses candidates’ clinical skills in standardised simulations of typical general practice. Approximately 4000 candidates (including resit attempts) are examined each year. Of those entering a GP training programme approximately 3% fail to complete the programme successfully, a minority of those being isolated CSA failures.

A common criticism of the previous RCGP membership examination was the fact that it did not contain an assessment of clinical skills. The CSA was developed in 2007 in this context, based on best evidence in assessment and was approved by the regulator. External reviews were sought in the early years from national and international experts in assessment. The RCGP carries out extensive analyses of examination data in order to refine and improve their assessments, and publishes an annual report with a full data set. It has always highlighted the relative performance of different candidate groups. These differentials are most marked between candidates whose primary medical qualification (PMQ) is from the UK (UKG) and international medical graduates (IMGs). In UKGs smaller but significant differentials exist in relation to black and minority ethnic (BME) status and sex. Those differentials also exist in other postgraduate and undergraduate examinations.2,3

In the light of these differential pass rates a judicial review of the RCGP and the GMC was requested by the British Association of Physicians of Indian Origin (BAPIO). The basis for the review were three claims: that the RCGP and GMC did not comply with their public sector equality duty (PSED), that the CSA directly discriminates against IMG and BME candidates, and that the CSA indirectly discriminates against IMG and BME candidates.

LEGAL CHALLENGE AND ITS OUTCOME

In April 2014 the Honourable Mr Justice Mitting heard the Judicial Review. In his judgement he dismissed all three claims concluding,

‘I am satisfied that the clinical skills assessment is a proportionate means of achieving the legitimate aim (of protecting the public) identified.’

In particular, in terms of the claim of indirect discrimination he ruled that:

‘There is no basis for contending that the small number who fail ultimately do so for any reason apart from their own shortcomings as prospective general practitioners.’

The Judge ruled that the RCGP although not a public authority, has a public sector equality duty (PSED) in respect of the conduct and award of the MRCGP, as it has the power to determine who meets the standards to be a GP in the UK, and this is a matter of public importance because of patient health impact. He suggested that the RCGP should now take actions within its own powers such as continuing to maximise the diversity of the panel of examiners and by using its influence with the training community to improve candidate preparation for the CSA.

The RCGP takes its PSED very seriously and is conducting a College-wide review of equality and diversity, seeking to apply the high standards required by the duty to all its appropriate functions.

DIFFERENTIAL ATTAINMENT: CAUSATION

In order to take action on differential performance by IMG and BME candidates in the CSA it is important to understand its causation. General practice in the UK is heavily dependent on the enormous contribution made by IMGs. In the 3 years from 2010 approximately 31% of those taking the MRCGP had qualified from outside the UK. Most IMGs will complete the Professional and Linguistic Assessment
“Doctors who are not equivalent at entry to GP specialty training are likely to struggle with the MRCGP unless they receive training that addresses their specific needs.”

Board [PLAB] exam before applying for GP specialty training. Two recent studies looking at the predictive validity of the PLAB exam in relation to MRCP and the MRCGP outcomes, and Annual Review of Competence Progression outcomes in a variety of medical specialties have concluded that the current standard of PLAB is set too low, and is below the competency level expected for a UK graduate completing foundation Year 1 training. Doctors who are not equivalent at entry to GP specialty training are likely to struggle with the MRCGP unless they receive training that addresses their specific needs.

It is harder to understand the differentials that exist between white and BME UK trained graduates, who have received similar training. These differentials are seen in the AKT, a machine marked test, and are mirrored by other studies from within the UK both at undergraduate and postgraduate levels within and without medicine, and despite extensive investigation no cause for these differences has been identified.

While the RCGP is responsible for the curriculum and MRCGP examinations, the deaneries/local education training boards (LETBs) are responsible for GP training. Published evidence has shown that performance in selection tests for training correlate with performance in the MRCGP exit examinations. Peile has suggested that appropriate inductions and support would help graduates from outside the UK. Many deaneries/LETBs utilise selection scores to identify trainees at risk of poor performance in the MRCGP in order to put supportive training interventions in place. While there is considerable good practice in various parts of the UK with regard to targeting training there has been no evaluation of the effectiveness of these interventions.

DIFFERENTIAL ATTAINMENT: SOLUTIONS

The RCGP recognises the pivotal role training programme directors and educational supervisors can play in candidate preparation for the CSA and has developed a number of measures aimed at supporting the training community. These include a programme for trainers to visit the CSA, and new resources for CSA preparation, based on sociolinguistic research by Kings College, London and Cardiff University. Two new e-modules and a book are planned for release in early 2015. The MRCGP exam will continue to develop in line with best practice in assessment to ensure that it remains a robust, fair, and defensible exam. The RCGP is currently working through a number of activities with continued development of quality assurance processes, feedback, and standard setting. As usual any changes will have to be approved by the GMC.

The Judicial review, although expensive and traumatic for all those involved has served to highlight differential attainment by IMG and BME candidates across the whole postgraduate medical education and to bring together all the major stakeholders with renewed emphasis on finding effective solutions. The RCGP will continue to remain at the forefront of this work.

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As the population ages, there is a pressing need to cost-effectively manage the care of increasing numbers of people with long-term conditions and prevent unnecessary hospitalisation. If we are to meet these needs as efficiently as possible in the future, we need to better understand the potential contribution of nurses working in general practice, and ask what we know about the efficacy and cost benefits of their contribution.

WORKFORCE DATA
In the 10 years since the introduction of the Quality and Outcomes Framework (QOF), the reported number of registered nurses employed in GP practices is estimated to have increased by 15%, and stands at 23,833 nurses in the equivalent of 14,943 full-time posts (Figure 1).1 Practice nurses make up over one-third (37%) of the clinicians in general practice.

Yet little is known about the ways in which practice nurses are deployed within each practice: their numbers, the mix relative to other practice staff, or level of specialist skills and experience. Although the NHS in England has started to collect and publish more data on the numbers of nursing staff employed by practices, the information is sparse. The GP workforce census for 2013 included 14 spreadsheets; 13 on general practice medical staff: roles, type of contract, qualifications, sex, age, country of qualification, work-hours, and size of practice. One worksheet covers nursing, administration and clerical, and other staff. And these data come with the caveat that ‘for those practices where data was not supplied (10%) an estimate has been made and those estimates are included in the figures’. Thus, both the quantity and quality of data on this workforce are meagre.

REGIONAL VARIATION
Analysis of these data suggests that there may be regional variation in practice nurse numbers: with one nurse per 3058 patients in North Central and East London, compared with 1973 patients per nurse in South West England. While these figures are patients per headcount, rather than per whole-time equivalent (which limits their value to some degree) they support earlier analysis2 that found a two-fold variation in the patient to registered nurse ratio between practices with the highest and lowest staffing levels (comparing the top and bottom quintiles).

TYPICAL PROFILE
Some insight into the practice nursing workforce can be gleaned from a cross-sectional survey of Royal College of Nursing nurses in 2009.3 They are typically older than other nurses, more experienced (26 years’ nursing experience compared to average of 17 years) and they are a relatively stable workforce with low levels of turnover. Practice nurses are less likely to hold a degree than other nurses (17% versus 33%) but the proportion with a degree had increased since a comparable survey in 2003 (10%). They are less well paid than other nurses (relative to their experience and the role and responsibilities held) but they nonetheless are one of the most highly satisfied groups of nurses. They report having more time to spend on clinical activity and greater levels of job satisfaction, with opportunities to take time off for professional development.

This survey suggests that general practices are offering a positive work environment for nurses and there may therefore be scope to continue to attract nurses into this field of nursing in the future, and, hence, increase the volume and range of work undertaken by practice nurses, should we want to. But do we? What do we know about the effectiveness of the contribution of nurses in general practice to date?

WORK AND WORKLOAD
The workload of practice nurses has been changing over the past 10 years with many nurses now dealing with more complex patient care.4 Nurses often provide a range of nurse-led clinics that allow for health promotion and surveillance of chronic disease such as asthma, diabetes, and chronic obstructive pulmonary disease (COPD). However, the cost implications of these changes remain unclear.5

Both the volume of work delegated by GPs to nurses and the proportion of consultations that are undertaken by practice nurses, is reported to have increased.4 Some have argued that there is considerable scope to further increase the amount of primary care delivered by nurses7 but the potential extent and desirability of substitution for GPs is contested.8

“Practice nurses make up 37% of the clinicians in general practice yet we know little about the ways in which they are deployed.”

Figure 1. Nurses in GP practices (FTE) 2003–2013.
Several studies have outlined the changes to practice nurses’ workload and their increased role in caring for those with chronic conditions such as diabetes. The results of controlled trials suggest that nurses can provide care for a number of patient groups that is of comparable quality to that of their medical colleagues. However these studies typically focused on nurse practitioners with specific specialised training, as opposed to practice nurses in general, and all examined services delivered within the tightly controlled parameters of clinical trials.

WHAT EFFECT ON OUTCOMES?

Research by the National Nursing Research Unit used the QOF to examine long-term conditions such as diabetes and found that higher levels of practice nurse staffing were associated with improved practice performance. The effect of practice nurse staffing remained after controlling for patient, practice, practitioner, and organisational factors, although factors such as support for education and training for staff appeared to be associated with far more variation than staffing levels. But we know little about the actual roles taken by nurses and the specialist training they have undertaken to fulfil those roles, which in the past has been highly variable.

While much attention is currently focused on nurse staffing and skill-mix in hospitals and the relationship to patient outcomes, we have a dearth of good quality data on the impact of the registered nurse contribution in primary care. As the number and contribution of practice nurses continues to increase we need to be asking what the effect is on patient outcomes, and collect more granular workforce data to help us answer questions about the optimal level and skill-mix of nurses in general practice and their contribution to patient care.

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“I have a dearth of good quality data on the impact of the registered nurse contribution in primary care.”