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EDITORIALS

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Electrocardiography in suspected angina

Poor at predicting future events but is still an essential part of assessment

RESEARCH, p 1272

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Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: *BMJ* **2008;337:a2340** doi: 10.1136/bmj.a2340



In the linked cohort study, Sekhri and colleagues assess whether resting and exercise electrocardiograms (ECGs) provide superior prognostic value to that obtained from the clinical history in ambulatory patients with suspected angina.¹ The study indicates that the clinical assessment accounts for most of the prognostic information provided by resting and exercise ECGs.

Other studies and algorithms have used the patient's pretest probability to help with diagnosis,² but long term prediction of risk and the incremental usefulness of the ECG have not been evaluated in this way.

The study is a reminder of the importance of taking a detailed history and making a thorough physical examination, and that additional information from the ECG is helpful in some patients but does not predict risk in everyone. The results do not mean that ECGs and stress tests are not useful, because an abnormal ECG and abnormal stress test independently predicted adverse events, such as death or acute coronary syndrome in the cohort studied.

Some patients with normal ECGs and stress test results subsequently had cardiovascular events; this shows that predicting risk in the longer term is difficult. In most patients presenting to a chest pain clinic a diagnosis is made on the basis of the history and examination. For example, a 55 year old man with classic exertional angina that is relieved with rest or nitroglycerine needs no further tests to confirm the diagnosis of coronary disease. However, a test is needed to distinguish between the shorter term and longer term prognosis, especially in people who have a normal stress test result but who subsequently have cardiovascular events (although Sekhri and colleagues' study indicates that the event rate is lower in these patients than in those with abnormal results). Attempts have been made at fine tuning the prognostic value of the basic treadmill test. Research in North America showed that the Duke treadmill score added prognostic information to a routine stress test.³ Other modalities, such as exercise echocardiography, have been added more recently to the Duke treadmill score to predict risk.⁴

Sekhri and colleagues also found that the duration of exercise is a stronger predictor than other variables in the model of future cardiovascular events. More sophisticated tests to assess left ventricular function and perfusion with stress imaging also have greater negative predictive value than a routine stress test.⁵⁸ However, from a population perspective this may be an unnecessary expense, and these tests may be more useful in selected groups of patients⁸ who have a higher pretest probability.

Sekhri and colleagues' study shows that although the short term cardiovascular event rates are lower in patients with a normal ECG and stress test, they are not zero. So the study cannot provide an answer about which approach should be used in patients with a normal ECG. These patients need to have their cardiac risk factors assessed regularly by their general practitioner, and if necessary modified. As the authors correctly say, the stress test and ECG are not foolproof predictors of risk, and other methods need to be tested. However even though these tests cannot predict all future events, they are a necessary extension of the physical examination in patients with suspected angina.

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BCG vaccination in children

Can be given percutaneously rather than intradermally, if necessary

RESEARCH, p 1275

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Competing interests: None declared

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: BMJ 2008;337:a2086 doi: 10.1136/bmi.a2086

More than 100 million doses of BCG vaccine are used each year worldwide. The role of this vaccine in the global control of tuberculosis has generated controversy for several decades and has often been underestimated. Although it has not curtailed the global epidemic, BCG immunisation in children has undoubtedly reduced childhood morbidity and mortality from tuberculosis. In the linked randomised controlled trial, Hawkridge and colleagues compare the effectiveness of intradermal versus percutaneous BCG vaccination in infants from birth to 2 years of age.¹

Four high quality trials have shown that BCG is about 70-80% effective in preventing disease when given to mycobacteria naive newborns.² Efficacy was lower in trials of older children and adults, but it now seems that such trials probably included subjects who had been exposed to mycobacteria despite having negative baseline skin tests (newer in vitro assays are more sensitive than skin tests in detecting previous infection with Mycobacterium tuberculosis or non-tuberculous mycobacteria³). Children or adults who have been exposed to mycobacteria are either already protected against tuberculosis or are unable to sustain the BCG replication needed for protection.4 Thus, the efficacy of BCG will be absent or low, and trials including these subjects should not be considered when assessing the efficacy of routine childhood immunisation with BCG.

Variations in efficacy have been proposed for different strains of BCG, with reduced efficacy seen for strains with greater numbers of serial passages.⁵ How-



ever, because almost all species of natural or vaccine induced mycobacteria that have been studied (BCG, M microti, non-tuberculous mycobacteria, M tuberculosis) seem to confer cross protection against the subsequent mycobacterial disease that has been studied (tuberculosis, leprosy, and disease from *Mulcerans* or *Mavium*),² differences in the efficacy of BCG are probably caused by differences in trial design rather than small genetic differences between substrains of BCG.6

Different BCG strains and different methods of BCG production have different patterns of local reactogenicity.7 Serious side effects, such as disseminated BCG, can probably occur with all strains and have been well documented. Where feasible, HIV testing is recommended before giving BCG to newborns. However, because such testing is not widely available in resource poor settings, routine use of BCG should not be curtailed until HIV testing is possible.8

Another important question is whether the method of giving BCG-intradermal injection or percutaneous multiple puncture-affects efficacy or side effects. Immunogenicity studies show that the intradermal route results in a higher frequency of scarring, skin test conversion, and in vitro immunogenicity.9 However, the efficacy of the two different methods has never been compared in a large trial.

In their study performed in South Africa, Hawkridge and colleagues found no significant difference in rates of tuberculosis in the first 2 years of life between intradermal or percutaneous administration of Japanese 172 BCG.1 Although immediate systemic symptoms, duration of drainage, and minor local reactions were not studied routinely, the authors found no significant differences in the incidence of the uncommon and more serious reactions for which BCG recipients sought medical care-lymphadenitis, keloids, and disseminated BCG. The authors comment that neither route of administration worked "particularly well," but this conclusion cannot be drawn in a study that had no placebo group.

Opinions differ on which method of administration is more practical and consistent. Intradermal injection needs considerable training to be carried out correctly, but percutaneous administration often results in inadequate delivery of vaccine because not all tines of the applicator may penetrate the skin.¹⁰ It is difficult to know whether routine percutaneous administration would be as effective as was reported by Hawkridge and colleagues.1 Because no validated surrogate of clinical protection is available, no test can show that immunisation has been effective.

The South African study had the virtue of providing explicit case definitions for paediatric tuberculosis to facilitate interpretation of the findings. Two modifications of the definitions would be useful in subsequent studies. Firstly, because this study was done in an endemic setting, where laboratories were handling many positive specimens and where cross contamination would have been possible, it would have been advisable to have a more rigorous definition of definite tuberculosis that required multiple colonies of *M tuberculosis* from a single specimen or multiple positive sputum specimens.¹¹ Secondly, although the authors' diagnostic algorithm is suitable for initial decisions about treatment, a research definition of clinical "probable" or "possible" tuberculosis should include criteria on the presence or absence of a radiological or clinical response to treatment.^{11 12} Nevertheless, the absence of a significant difference in the rate of the most rigorously defined end point, definite tuberculosis, supports the non-inferiority of the percutaneous method in this particular research setting.

Should national policies be influenced by the present study? If health workers can be appropriately trained, the intradermal route remains the most reliable and safe method of giving BCG. But percutaneous administration can now be considered an effective alternative when other considerations make it preferable, although high quality applicators and standard methodology are necessary.

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Competing interests: None declared. Provenance and peer review:

Commissioned; not externally peer reviewed.

Cite this as: *BMJ* **2008;337:a2320** doi: 10.1136/bmj.a2320

Falls in older people are frequent and serious. This is particularly so for those in their 90s as the linked study by Fleming and colleagues shows.¹ Of their cohort, 60% fell within a year, 80% were unable to get up after a fall, and 30% had lain on the floor for an hour or more. Of those who were alone when they fell, 80% did not activate their alarms.

Consider lowering the risk of injury as well as lowering the risk of a fall

Fall prevention programmes decrease but do not eliminate the risk of an older person falling.² Falls remain frequent even in trial intervention groups. Also many older people at risk of falling do not think prevention programmes are relevant to them.³

As well as needing to improve the effectiveness, availability, and acceptability of fall prevention programmes, we need to find ways of lowering the complication rate from falls, particularly long periods spent lying on the floor and the direct effects of the impact.

Risk factors for lying on the floor for a long time are similar to those for a fall.⁴ Muscle weakness and poor balance are important and can be improved by strength and balance retraining programmes.² Some programmes now include instruction on getting up from the floor.⁵

Severe cognitive impairment is strongly associated with lying on the floor for a long time.¹ Mild cognitive impairment, which affects executive function, planning, and spatial orientation, may predispose to the fall.⁶ Such subtle preclinical loss may also impair the older person's ability to get back up, especially if he or she is injured, is in the dark, or has taken a sedative.

Planning, instruction, and practice in the person's own home may help. The directions should be simple, the climbing up points identified, and the manoeuvres well practised. This can be presented as being similar to the training of the professional athlete who adopts a positive mental attitude and "visualises" the event in preparation. As yet, no trial evidence is available for this strategy, but consideration should be given to testing such an approach in a large fall prevention trial. Problems of planning, coordination, and execution may also prevent older people from activating their alarms. Nothing is simple when you are upset, disoriented, and dealing with a technological device that you never wanted in the first place and only wear at your family's insistence. Rather than just accept the most commonly voiced reason for not using an alarm-"I didn't want to trouble anyone"we should pay more attention to simplicity of design, practice, and availability of the alarm after the fall.

In older people at risk of fracture, treatment of osteoporosis, including vitamin D supplements, and protective measures need review. Hip protectors are the most thoroughly investigated physical measure to reduce injury after a fall, and they reduce the risk of fracture by 80% if worn at the time of the fall.⁷ Hip protectors have a role for the individual at particular risk of

fracture who is willing to wear them most of the time.

The NHS has plans to increase the availability of measures to prevent injury that do not rely on the action or adherence of the older person.⁸ However, the introduction of electronic surveillance into practice has been difficult because of organisational complexity and lack of efficacy and acceptability.⁹ Devices that detect sudden changes in posture or provide continuous visual monitoring are technically feasible but have not been adequately tested in daily practice.¹⁰¹¹ Automatic alarms and surveillance systems must be in action at all times and places, including the shower and toilet, and have a high sensitivity and low false alarm rate.

Impact absorbent floor coverings can reduce the impact of the fall without affecting stability,¹² but they need pragmatic testing in high risk settings. Testing will be expensive and require partnerships between commercial enterprises and research centres.

Fleming and colleagues' study should trigger an alarm. People over 90 and those with even subtle cognitive impairment are vulnerable. We can lower the risk of falling and of injury by developing plans for individuals. But in the longer term, we need collaborative research between health professionals, particularly rehabilitation staff, and the commercial sector.

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International regulation of alcohol

A framework convention is needed, as for tobacco control



Cite this as: *BMJ* **2008;337:a2364** doi: 10.1136/bmj.a2364

The World Health Organization's Commission on Social Determinants of Health has just issued its main report,¹ which lays out an ambitious programme of actions to tackle health inequity. The commission notes the substantial contribution of alcohol to injury, disease, and death worldwide,² and it proposes that WHO and member nations should use the 2005 framework convention on tobacco control as a model for alcohol control. We agree that it is time to adopt such a framework.

The commission's work underscores the urgent need for international agreements that promote alcohol controls throughout the developing and developed world. Increasing affluence in the fastest developing regions of the world–East Asia, the Pacific region, and South Asia—has led to increased alcohol consumption, along with a higher burden of harm caused by alcohol. These increases foreshadow future trends in consumption and harm for other developing countries—such as those in Africa, Central America, and South America—if and when increased affluence makes them attractive untapped markets for global alcohol producers and distributors.³⁴

In developed countries, alcohol is widely and readily available, and the real prices (minutes of work needed to buy one drink of alcohol) have decreased. Greater availability causes more health and social harm,⁵ and the increase in availability seems to be associated with greater health inequity.⁶⁷ At the same time, the spread of free market ideology and intergovernmental trade agreements has undercut the ability of nation states to control alcohol related harms through controls on marketing, monopolies, and tax policies.⁸ To counterbalance the globalisation of alcohol trade, we need international agreements that protect public health.

The irony is that we know more today than ever about which strategies can effectively control alcohol related harms.⁵⁹ But policymakers have been slow to put this knowledge into practice. Policies that tax alcohol and restrict its availability, marketing, and distribution—thereby reducing alcohol related harm—are strongly supported by evidence. Evidence that such policies can also reduce related health inequities is limited but growing.⁷ Despite this knowledge, policymakers still rely mainly on public information campaigns and education programmes, most of which have been shown to be marginally effective.⁵

A framework convention for alcohol control would protect public health in three ways. Firstly, such a convention could place restraints on international trade in alcohol. Although most alcohol is consumed in its country of origin,³ alcoholic drinks are still an important trade item. Current international trade agreements and dispute adjudications tend to treat alcohol like any other commodity. This ultimately Robin Room professor, School of Population Health, University of Melbourne, and AFR Centre for Alcohol Policy Research, Turning Point Alcohol and Drug Centre, Fitzrov, VIC 3065, Australia Laura Schmidt associate professor, Philip R Lee Institute for Health Policy Studies and Department of Anthropology, History and Social Medicine, School of Medicine, University of California, San Francisco, CA 94118, USA Jürgen Rehm professor and section head, Dalla Lana School of Public Health and Department of Psychiatry, University of Toronto, and Section on Public Health and Regulatory Policies, Centre for Addiction and Mental Health, Toronto, ON, Canada, M5S 2S1 Pia Mäkelä senior researcher Alcohol and Drug Research Group, National Research and Development Centre for Welfare and Health (STAKES), 00100 Helsinki, Finland

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed. breaks down national and local controls on the alcohol market^{10 11}—the very policies that can effectively promote public health. In a globalising world, one of the strongest arguments for international agreements is the need to control cross border trafficking of alcohol. A framework convention for alcohol "would provide an international community of support" for effective policies and could "add weight to the defence of such policies under trade disputes."¹²

Secondly, the adoption of a framework convention for alcohol control is likely to have persuasive effects across all levels of government and society. Most provisions in the current framework for tobacco are voluntary—countries signing up are urged to consider the measures but do not have to implement them. Nevertheless, such international treaties become calls to action and road maps to help legislators and governments to learn about and implement effective evidence based policies.¹³

Finally, framework conventions commonly become a base of operation for a secretariat and oversight committees charged with making the mechanisms and provisions of the convention more effective.¹³ A secretariat for the convention could, for example, establish an international clearing house of information on evidence based approaches to alcohol control, thus providing an infrastructure for knowledge sharing between countries and regions.

Alcohol is the only strong psychoactive substance in common use that is not controlled internationally. Tobacco has the 2005 framework convention, plant based drugs have the 1961 single convention, and psychopharmaceuticals have the 1971 convention on psychotropic drugs. We now have sports doping conventions for psychoactive substances used as performance enhancers.¹⁴ Yet the global health and social burdens attributable to alcohol are greater and affect the poorest populations and nations of the world disproportionately. The WHO commission's call to apply the model of the framework convention on tobacco control to control of alcohol is well founded and timely.

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Global research for health

Should tackle health needs and inform policy

Last week delegations from 59 governments, international agencies, and researchers met in Bamako, Mali, to discuss the state of global health research. It was an opportunity to review progress since their last meeting, four years earlier, in Mexico City, and to set an agenda for the future.¹ The meeting in Mexico is widely seen as a turning point, where the importance of research tackling the greatest health needs was emphasised, and where a strategy for meeting these needs was proposed.

Arguably, in a world with scarce resources efforts should be focused on where they can do most good. To make this happen, those attending the conference in Mexico advocated greater investment in research on health systems and policy, the development of national health research policies, and the incorporation of evidence into health policy.

The consensus is that some progress has been made since Mexico. Funding for health systems and policy research has increased, and some politicians now accept that evidence based policies are desirable.² Yet we still have much to do. The births, lives, and deaths of many of the world's population remain unrecorded.³ Large scale programmes and healthcare reforms are still implemented without evaluation.⁴ The reasons why they succeed or fail are often unknown. And large parts of the world are effectively untouched by health research.

One purpose of a meeting like this is to facilitate dialogue among groups of people who might not otherwise meet. In this it succeeded. Governmental delegations heard about the opportunities offered

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attended the Bamako conference on behalf of the European Region of WHO. He is a member of WHO's advisory committee on health research and has recently completed a term as a member of the Wellcome Trust's population and public health panel.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: *BMJ* 2008;337:a2733 doi: 10.1136/bmj.a2733

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IVEK PRAKASH/REUTERS

by health research and the obstacles to achieving them, in some cases seemingly for the first time. Although good intentions often collide with financial and political realities at home, many remarks made by ministers indicated that they had taken the messages on board. But what did the meeting achieve?

The most tangible outcome was a "call to action."⁵ In it, governments committed themselves to developing health research strategies and to funding them adequately, allocating at least 2% of the budgets of their ministries of health. They also committed to creating research infrastructure, including ethical review procedures, clinical trials registries, and open access to data, while promoting knowledge translation as a means of developing evidence based policies. Finally, they accepted the need to build a critical mass of young researchers. Others must also play a role. International development agencies are called on to devote at least 5% of their spending on health to development of research capacity, while they and research funders should pursue innovative financing mechanisms and align their support with national plans.

So what next? The call to action sets out an ambitious agenda, but so did the declaration at the Mexico City summit. An immediate need is to establish a monitoring mechanism that can track progress against stated intentions, so that next time it will be possible to assess what has been achieved and by whom. It is not obvious who should undertake this role, and that fact argues for a reassessment of the often confusing roles of the different bodies that oversee global health research. Yet whoever does it, they should report regularly and publicly, so that governments can be held to account by their populations.

The widespread view was that research funding must change. Short term project based funding should coexist with long term investment in research capacity. Research portfolios should be balanced; they should include basic and applied research, as well as generalisable and context specific studies. These last studies are often the ones that make the greatest difference. The importance of knowledge transfer was stressed, and successes such as the Evidence-informed Policy Network were given as examples.⁶

Calls were also made for partnerships, in which researchers would work with governments, civil society, and more controversially, the drug industry. The last of these stimulated the greatest debate. A few speakers highlighted past transgressions by the industry, seemingly implying that the growth of clinical trials in developing countries was in itself a bad thing. But as Mark Walport, director of the Wellcome Trust, noted, it is industry that makes the drugs that save lives, not academics. Another area of debate was the role of national research strategies. These are clearly important but should not exclude innovative investigator led research.

The real challenge will be within countries. One of the most striking images was a map of the world, which showed research capacity.⁷ The heaviest shading was, as expected, in the developed countries of Europe, North America, and East Asia. Large parts of the map were completely empty, however, in west and central Africa, the Middle East, and the former Soviet Union.

The unresolved challenge is what we should do where there is virtually nothing to build on. Increasing global funding alone will not help. External donors can help, if they are willing to invest strategically and recognise that the results of their funding may take a decade or more to become apparent. However, governments must also act, by tackling the corruption and failures of governance that prevent not just the development of health research but also the development of the basic institutions needed for anything to work.

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