

# BMJ

## Validating prediction models

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## OVER THE COUNTER MEDICINES

### Don't include trimethoprim

The Medicines and Healthcare Products Regulatory Agency (MHRA) moves to recommend, for the first time, that a systemic antibiotic (trimethoprim) should have its licence reclassified from prescription only medicine (POM) to pharmacy (P) availability.<sup>1</sup> For systemic antibiotics particular concerns exist that do not apply to other medicines.

The use of antibiotics may have an adverse effect not only on the specific patient but also on the public health of the community. Quantifying the relation between antibiotic exposure and resistance is difficult, but a case-control study of risk of an antibiotic resistant *Escherichia coli* urinary tract infection found that the risk of a trimethoprim resistant infection was significantly associated with a trimethoprim prescription in the preceding month (odds ratio 13.91 (95% confidence interval 3.32 to 58.31) if the prescription was for  $\geq 7$  days, and 4.03 (1.69 to 9.59) if the prescription was for  $< 7$  days).<sup>2</sup>

Because resistance to multiple agents is often linked, the selective pressure of using one antibiotic will often select for resistance to other unrelated agents. Data from the Cardiff area show that trimethoprim resistant coliforms are significantly more resistant to second line treatments such as ciprofloxacin (see table). Thus trimethoprim use will select for ciprofloxacin resistance.

There is also an issue of selecting resistance in organisms other than those targeted by treatment since most commensal flora will also be exposed to some degree to a systemic antibiotic. Trimethoprim is an oral option for treating various infections caused by methicillin resistant *Staphylococcus aureus* (MRSA).<sup>3</sup> Although rates of resistance are significant (35%) in UK bacteraemia isolates,<sup>3</sup> resistance among community isolates of MRSA in some areas (for example, south Wales) remains low at 12%. Increased trimethoprim use in the community is likely to select for resistance in MRSA and hence remove a valuable oral therapeutic option.

For these reasons, and for the growing concern about *Clostridium difficile* associated disease in the community, antibiotic use must be regulated to minimise inappropriate use. Restricting systemic antibacterial agents to prescription only has been recommended by the European Commission (2002/77/EC) and a House of Lords select committee.<sup>4</sup>

Given the ever-increasing restrictions on antibiotic use in hospitals that are being encouraged by the Department of Health in an effort to control resistance and *C difficile*, it seems paradoxical to reclassify trimethoprim.

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**Competing interests:** None declared.

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## DIRECT TO CONSUMER ADVERTISING

### A cynical consultation exercise?

The dismal proposals to allow pharmaceutical companies to promote prescription drugs directly to consumers have been orchestrated by the European Commission's Directorate General for Enterprise and Industry (DGEI).<sup>1</sup>

The DGEI's main objective is to promote European trade and economic development, which presents grotesque conflicts of interest when it comes to shaping health policy. DGEI greatly overestimates the support the proposals deserve, no doubt partly in the expectation of strong backing from the industry-funded patient groups that it has traditionally promoted.

The consultation document lacks any coherent health impact assessment. It blurs the distinction between high and low quality information, and takes no account of the health impact of the far greater quantities of partial information to which people will now be exposed. That is a crucial omission.

The activities of the leading pharmaceutical companies mainly distract from the health problems we face. Though sometimes extremely valuable, drugs can only ever be a small part of the solution.

DGEI fails to appreciate that you paralyse the healthy human response once people come to believe that their genes, body chemistry, and social/cosmetic camouflage are key to developing health and wellbeing. These proposals absurdly take for granted the benefits of technological and medical intervention. Health is to do with eating sensibly and sufficiently, taking enough exercise, avoiding toxic exposures, and having social security and justice. Disease awareness propaganda distracts from these imperatives.

It is folly to promote drugs as if they were the bedrock of health development and the key to maintaining good enough personal confidence, social equilibrium, and mental and physical health. Medicalisation not only makes people feel resourceless and ill but also threatens the very existence of national health services by creating unsustainable demand.

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- 1 Richards T. Purely medicinal? *BMJ* 2008;336:693. (29 March.)

### Resistance rates for community urinary coliform isolates from the Cardiff area

	% resistant				
	Amoxicillin	Co-amoxiclav	Cefalexin	Nitrofurantoin	Ciprofloxacin
All coliforms	52.6	13.1	7.2	14.1	8.1
Trimethoprim resistant coliforms	81.1	23.5	23.5	21.8	22.0

## Include cost of treatment

Practising in the United States, I am well acquainted with direct to consumer advertising of prescription drugs.<sup>1</sup> I suggest (and have suggested in the past to the Food and Drug Administration) that if such advertising is allowed, it should be mandatory for the manufacturer to state the typical cost of a course of treatment with the drug. My own experience of the \$600 (£300; €385) treatment for onychomycosis was that this information could save a great deal of time in explaining to the patient why the drug is not covered by their insurance. It could also prevent a whole unnecessary discussion in the first place as patients quite readily recognise that the cost is out of proportion to their problem.

There is one other problem: the (very reasonable) requirement that side effects and contraindications are mentioned in the advertising fails to put them in proportion. Thanks to television advertisements, patients are universally convinced that statins are likely to damage their livers, and many are reluctant to take this class of drugs for that reason.

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## UKCAT AMONG THE PIGEONS

### Undermining access ...

I am a student who hails from a low socioeconomic area in south Wales who knows first hand the fears that students hold regarding student debt. I think that UKCAT is nothing more than a divisive sieving exercise further to increase the divide between those who can and cannot afford to study medicine—a degree already overburdened with student debt and, now, uncertainty over postgraduate prospects and job security.<sup>1</sup>

Forcing medical students to pay the fee to undertake the test so that universities can

validate its accuracy is unethical and unfair. You would not expect patients to pay to take part in a clinical trial surely?

Within a few years revision courses will have been developed that will include “how to do well at UKCAT”—yet again probably increasing the divide between the affluent and less affluent, the public schools and state schools, and those in the know from most school leavers.

Gaining entrance into medical school should be based on talents, academic ability, and overall thirst to learn. Face to face discussions are the best way to tease out the personality traits that are considered fundamental for doctors, allow their personal statement claims to be validated, and for the medical school to get an overall impression of applicants’ attitude, personality and ability. With communication skills being emphasised more and more in the undergraduate curriculum surely the interview serves as a perfect way to kick start that process.

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<sup>1</sup> Cassidy J. UKCAT among the pigeons. *BMJ* 2008;336:691-2. (29 March.)

## ... and excluding the empathic

Beyond the technical difficulties of the UKCAT system there are wider areas for concern if UKCAT scores are widely used to screen medical school applicants.<sup>1</sup> There is a longstanding shortage of medical students interested in pursuing a career in psychiatry and a chronic shortage of consultant psychiatrists.<sup>2</sup> The UKCAT screen is actually entirely a test of technical reasoning skills, and its use as a discriminating tool will surely distort the strengths shown by medical students, so that we are attempting to train a group of junior doctors selected to have exceptional but narrow skills and aptitudes.

Medicine requires a broad range of human abilities, some extremely difficult to assess in any computerised test. Valuing what is measurable (reliably) is a catastrophic error compared with measuring (imperfectly) what is valuable. We must question whether we are drifting towards medical schools filled with potential surgeons and physicians and empty of general practitioners and psychiatrists.

Would you want to be cared for by Dr House?

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<sup>1</sup> Cassidy J. UKCAT among the pigeons. *BMJ* 2008;336:691-2. (29 March.)

<sup>2</sup> [www.rcpsych.ac.uk/researchandtrainingunit/centreforappliedresearch/completedprojects/careerintentionsinpsychiatr.aspx](http://www.rcpsych.ac.uk/researchandtrainingunit/centreforappliedresearch/completedprojects/careerintentionsinpsychiatr.aspx)

## HEALTH OF THE WORKERS

### Sick sick notes (sic)

We take exception to Snashall’s use of the word “farical” in his description of the sick note system.<sup>1</sup> It is not a word used in Dame Carol Black’s report,<sup>2</sup> and is not helpful. General practitioners have other minor considerations to take into account—such as diagnosis, treatment, and management of the patient’s medical condition that may be regarded by patients, society, and most of the medical profession to take precedence over occupational health matters. Having said that, however, GPs are all well aware of the health benefits of work and the damaging effects of a patient over-enthusiastically adopting the “sick role,” so it is normal practice to make some attempts to encourage a return to work, both for the patient’s as well as the employer’s benefit.

In an ideal world, the GP would communicate with an employer to gain background information about the working environment and to discuss possible measures to encourage an early return to work, but the NHS does not have the time and is not funded for this. The proposal to integrate occupational health into mainstream medicine runs the risk of extra work with no resources.

The government or employers need to develop a properly funded and professionally structured occupational health service which can positively liaise with primary care.

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<sup>1</sup> Snashall D. Health of the working age population. *BMJ* 2008;336:682. (29 March.)

<sup>2</sup> Black C. *Working for a healthier tomorrow*. London: Stationery Office, 2008. [www.workingforhealth.gov.uk/documents/working-for-a-healthier-tomorrow-tagged.pdf](http://www.workingforhealth.gov.uk/documents/working-for-a-healthier-tomorrow-tagged.pdf)

## Another ethical muddle for GMC

I note that it is now acceptable for a highly respected senior occupational physician to use the phrase “unaudited farce” in public and in the *BMJ* in relation to sick notes.<sup>1</sup> A major part of the workload of many occupational physicians entails sickness absence, and much of this entails disagreeing with the advice given by general practitioners via sick notes. In most areas of medicine, specialist doctors guide and advise generalists. To employ one doctor just to disagree with another is an unusual concept in health care.

The reason for this is said to be ethics. GPs are ethically obliged to be the patient’s

advocate, so when patients say they do not feel well enough to work, the GP is expected to support them. A fine principle perhaps, but clearly much abused. GPs say that advising on fitness to work is an area they are untrained for. Often, however, the issue is not a challenging medical decision; the patient has long since recovered (if there ever was any disease process), and they now have nothing medically important wrong with them. The argument therefore hinges on “ethics” and the distinction between giving patients what they want, or giving them what they and society need. For ethics to create such a conflict at a suggested cost to society of several billion pounds a year suggests a profound ethical muddle.

As the General Medical Council holds the key responsibility for medical ethics in the United Kingdom, this suggests that it holds a trump card for the solution to a substantial percentage of sickness absence in the country. This was not made clear in the Black report,<sup>2</sup> but it is an area worth exploring further.

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- 1 Snashall D. Health of the working age population. *BMJ* 2008;336:682. (29 March.)
- 2 Black C. *Working for a healthier tomorrow*. London: Stationery Office, 2008. [www.workingforhealth.gov.uk/documents/working-for-a-healthier-tomorrow-tagged.pdf](http://www.workingforhealth.gov.uk/documents/working-for-a-healthier-tomorrow-tagged.pdf)

## Sick note, fit note, no note?

Snashall's description of the current sick note system as an unaudited farce demonstrates a delightful but unusual honesty.<sup>1</sup> *Working for a Healthier Tomorrow* pins considerable faith on moving to a “fit note.” It is unrealistic for general practitioners to be expected not only to assess health but also to understand the detail of job requirements, which may be well outside their personal experience, within a brief consultation.

It's time to demedicalise the process wherever that is possible. Recognition began in 1982 with the extension of self certification from the first three days to the first seven days of absence from work. There is no good reason why this period could not be extended.

A recent small trial in our business, whereby the requirement to submit a sick note was replaced with the offer of early support and assessment by occupational health, was received very positively. The workforce felt a greater degree of trust (rather than the usual suspicion) was being shown towards them by management; and there was even a small reduction in lost working days over the six month trial period.

The problem is substantial. The solution

will not come from tinkering within existing systems.

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Competing interests: MD has been invited to take part in discussions with Dame Carol Black's department regarding early interventions in the workplace.

- 1 Snashall D. Health of the working age population. *BMJ* 2008;336:682. (29 March.)

## PREDICTING CITATIONS

### Validating prediction models

Lokker et al presented an interesting model to predict citation counts for clinical articles.<sup>1</sup> This topic is so important that the paper will probably attract many citations. We want to clarify some of the nomenclature of validation of prediction models, to avoid confusion in future reporting.

The authors randomly divided 1274 articles into a derivation data set of 757 articles for development of a prediction model and a validation dataset for testing of 504 articles, after exclusion of outliers with >150 citations. This procedure is an example of a split sample approach, but the authors refer to it as cross validation. Cross validation would mean that we develop a model in the first part of the data and test it in the second part, and then repeat the procedure with development in the second part and testing in the first.

The authors report that explained variation (R<sup>2</sup>) decreased from 0.60 at development to 0.56 at validation, and refer to this decrease as shrinkage. Shrinkage is not an appropriate term for this decrease; a better label is optimism.<sup>2,3</sup> Optimism is the phenomenon that prediction models tend to perform more poorly in new data than in the data where the model was developed; it occurs especially when many predictors are considered in relatively small datasets.<sup>4</sup>

Ironically, a need for shrinkage is well illustrated in figure 2, where the residuals are generally positive for low predictions (which were often too low), and generally negative for high predictions (which were often too high).<sup>1</sup> Shrinkage should be applied to the regression coefficients for more reliable predictions.<sup>2,4,5</sup> How valid is this model to predict citations? Firstly, the authors did not shrink regression coefficients, which implies that high predictions will be too high and low predictions too low for articles fulfilling the inclusion criteria. Secondly, for a future article we cannot know beforehand whether the article is an outlier, i.e. having more than >150 citations. Exclusion of outliers at validation is artificial and should not have been done; it has inflated the R<sup>2</sup> of the model. As

always with prediction models, future validation is required and may reveal disappointing performance.

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## DITCHING IMPACT FACTORS

### Time for the single researcher impact factor

It is indeed time to consider alternatives for the “impact factor” algorithm.<sup>1</sup> For example, it might be more useful to consider the merits and contributions of all the scientific activities of each single researcher instead of measuring only the impact factor numbers. For example, as reported in a recent debate in *Science* about peer reviewers' responsibilities,<sup>2</sup> writing and finalising an article is a complex process in which reviewers offer a crucial scientific contribution. One possible solution is to create a new index, the single researcher impact factor, which can take into account the number and quality of traditional publications and other activities such as reviewing manuscripts.

Some experimental versions of this new index are under evaluation. The single researcher centred impact factor will ensure that the evaluation of individual scientific impact in the community will be more accurate and could better motivate researchers to review (without frustration), publish, and share their ideas.

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Competing interests: None declared.

- 1 Hobbs R. Should we ditch impact factors? *BMJ* 2007;334:569.
- 2 Perrin WF. In search of peer reviewers. *Science* 2008;319:32.



## GYNAECOMASTIA

## Drugs and surgical concerns



P. MARAZZI/SPL

Niewoehner and Schorer do not mention the long list of drugs which can be associated with gynecomastia, especially in elderly patients.<sup>1</sup> A list (produced by the pharmacy of the Norfolk and Norwich University Hospital in 1993) has 69 drugs on it, including the commonly prescribed drugs allopurinol, amitriptyline, atenolol, ciprofloxacin, chlorpromazine, digoxin, enalapril, furosemide (frusemide), nifedipine, verapamil, and warfarin (the list is far too long to be included in a letter). In clinical practice, medication is the commonest cause of gynecomastia in elderly patients.

One important point relating to surgical technique when removing excess breast tissue in young men should also be mentioned: excising all the abnormal breast tissue will result in an unsatisfactory cosmetic outcome as the enlarged breast will be replaced by a dent. A sufficient slice of breast tissue should be left to prevent this happening, and I have never encountered recurrent gynecomastia despite adopting this technique over many years.

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- 1 Niewoehner CB, Schorer AE. Gynecomastia and breast cancer in men. *BMJ* 2008;336:709-13. (29 March.)

## Are surgical guidelines realistic?

Surgery is considered to be a low priority aesthetic procedure in benign gynecomastia<sup>1</sup> and in the UK has risen by 27% in 2007 in comparison to 2006.<sup>2</sup> In some regions affected men would not be offered surgical treatment on the NHS.<sup>3</sup> Our 2006 regional guidelines suggest that 200 g of tissue should be excised from each side to warrant surgery on the NHS. Our audit of 48 men who underwent surgery for benign gynecomastia on the NHS between 2003 and 2006 found that only three would have met the guideline criteria for surgery on the NHS. We wonder whether the government guidelines are realistic.

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- 1 Niewoehner CB, Schorer AE. Gynecomastia and breast cancer in men. *BMJ* 2008;336:709-13. (29 March.)
- 2 BAAPS Statistics 2007. [www.baaps.org.uk/content/view/280/62/](http://www.baaps.org.uk/content/view/280/62/)
- 3 Oxfordshire NHS Trust Priorities Forum policy statement. [www.oxfordshire.nhs.uk/docs/lavender/policy6b2.pdf](http://www.oxfordshire.nhs.uk/docs/lavender/policy6b2.pdf)

## ROBOTIC PROSTATECTOMY

## Data, please

This was an interesting article about attempts to encourage developments in robotic surgery.<sup>1</sup> But the story was completely devoid of any data.

We learn that robotic radical prostatectomies are much more common in the US than in the UK but we learn nothing about outcomes. We learn that there are ethical issues, but none is specified. We learn that a urologist believes robotic surgery has several advantages. But those are not quantified. What does "better results" mean?

We learn that "patients recover more quickly" but we're not told how many patients. We learn of "better cancer control" without any definition of that term.

Ditto for reported claims of more precision, "less collateral damage, resulting in less blood loss, faster recovery, and fewer complications." No numbers.

I'm trying to teach my health journalism students, "No numbers? No story." I hope they weren't reading this week's *BMJ* News section.

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- 1 Mayor S. Robotic prostatectomy transmitted live to engineers to promote collaboration. *BMJ* 2008;336:687. (29 March.)

## GMC GUIDANCE ON BELIEFS

## Denies conscientious objection

The recent ethical guideline of the General Medical Council puts doctors in an impossible position.<sup>1</sup> The giving of information or aiding someone to obtain a service the doctor considers immoral contravenes the essence of conscientious objection. The doctor's right to have his moral code respected, provided that it isn't spurious or lacking a credible evidence base, is a basic human right.

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**Competing interests:** None declared.

- 1 Dyer C. Doctors must put patients' needs ahead of their personal beliefs. *BMJ* 2008;336:685. (29 March.)

## MULTIPLE HEALTH PROBLEMS

## Presentation is important too

Anwar et al point out that weaknesses in the healthcare system can disadvantage the patient with multiple health problems.<sup>1</sup> However, there is evidence that the way in which a patient presents might influence whether a particular problem is seen as a priority, a secondary issue, or overlooked altogether. In a study of a videotaped general practice consultation of a male patient with physical, emotional, and social problems, 27 general practitioners were asked to give a diagnosis in their own words.<sup>2</sup> The patient's medical records showed deteriorating cardiac and pulmonary disease over the previous eight years. However, the patient presented in an angry and distressed manner. As a consequence, most of the GPs picked up on the psychological issues, but many failed to note the patient's heart problems.

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- 1 Anwar R, Gogi N, Anjum SN. Do we neglect patients with multiple health problems? *BMJ* 2008;336:670. (22 March.)
- 2 Jenkins R, Smeeton N, Marinker M, Shepherd M. A study of the classification of mental ill-health in general practice. *Psychol Med* 1985;15:403-9.

## COMPUTER SAYS YES

## Let the patient decide

Spence describes a real example of the difficulty we have as humans coping with the implications of statistics.<sup>1</sup> The patient is at high risk because he falls within certain parameters that have been abstracted from analysis of large amounts of data. He may not look that shape when seen in total, but when refracted through the lens of that risk assessment tool, he does.

The patient needs to be told that he is at an increased risk of x and would obtain a benefit of y if he took drug a for z years. He should be told that with the best available risk and costbenefit analysis, the NHS is happy to pay for him to have this treatment. He can then take responsibility for his own health and hopefully save his general practitioner the stress of deciding whether to insist on it or not.

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**Competing interests:** None declared.

- 1 Spence D. Computer says yes. *BMJ* 2008;336:724. (29 March.)