RESEARCH

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SPECIALTY IN THE SPOTLIGHT—the *BMJ* Olympics portal

The Olympic games are well under way in London, and we have been publishing more about sports medicine than usual across our many publications and products. The *BMJ* Olympics portal features selected material from the *BMJ*, BMJ Journals, BMJ Learning, doc2doc, blogs, podcasts, and videos. From now until the end of the Olympics and Paralympics you can access some of our best resources on sports medicine in one place. Join in the discussions on our Olympics forum and catch up with the latest on the track and other Olympic venues with our tweets, by visiting bmj.com/Olympics

Recently published

Adductor injury in sport—in association with the *BJSM*

The evidence underpinning sports performance products: a systematic assessment

The truth about sports drinks

RESEARCH RESPONSE ON BMJ.COM

It's good to see a good quality trial question the effectiveness of speech and language therapy for stroke associated aphasia. But it was worryingly expensive. According to the HTA website it cost £1.5m to recruit 170 participants—nearly £9000 per recruit!

If the NHS stops funding this ineffective treatment it may turn out to be money well spent. But will they? Thirty years ago David and colleagues did the same trial with the same result.[1] Speech therapists ignored that trial then.

Jim G Thornton, obstetrician gynaecologist, University of Nottingham, Hucknall Road, Nottingham

Jimgthornton@hotmail.co.uk
www.ripe-tomato.org

1 David R, Enderby P, Bainton D. Treatment of acquired aphasia: speech therapists and volunteers compared. *J Neurol Neurosurg Psychiatry* 1982;45:957-61.

RESEARCH ONLINE: For these and other new research articles see www.bmj.com/research

Shift work and vascular events: systematic review and meta-analysis

Shift work is associated with an increased risk of major vascular problems, such as myocardial infarction, coronary events, and ischaemic stroke. Manav V Vyas and colleagues analysed 34 studies which involved 2 011 935 people. They say that the relative risks are modest, but the population attributable risks are high and this may have implications for public policy and occupational medicine.

Risk of cancer with metal-on-metal hip replacements

This Finnish population based study found that metal-on-metal hip replacements are not associated with an increased overall risk of cancer during a mean follow-up of four years. The authors followed up 10 728 patients who underwent metal-on-metal total hip arthroplasty and 18 235 patients who underwent conventional metal-on-polyethylene, ceramic-on-polyethylene, and ceramic-on-ceramic total hip arthroplasty. They found a suggestion of an increased risk of basal cell carcinoma and sarcoma at the early stage of follow-up, but they say that this could be a chance finding. (*BMJ* 2012;345:e4646)

Weight gain in smokers after quitting cigarettes: meta-analysis

Henri-Jean Aubin,[1 2] Amanda Farley,[3] Deborah Lycett,[3] Pierre Lahmek,[2] Paul Aveyard[3]

EDITORIAL by Fernández and Chapman

[1]Centre d'Enseignement, de Recherche et de Traitement des Addictions, Hôpital Paul Brousse, AP-HP, Univ Paris-Sud, INSERM U669, 94804 Villejuif, France
[2]Centre de Traitement des Addictions, Hôpital Emile Roux, Limeil-Brévannes, France
[3]UK Centre of Tobacco Control Studies, Primary Care Clinical Sciences, University of Birmingham, Birmingham, UK
Correspondence to: H-J Aubin
henri-jean.aubin@pbr.aphp.fr

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Response on bmj.com

"In our view, it is unhelpful to sidestep the consequences of smoking cessation when framing public health messages, as this will simply undermine the credibility of these messages to the general public. People believe that smoking helps them to control weight—not only is this correct, but it is also counterproductive not to work with people's beliefs about the potential health effects of behaviour in the context of health promotion." Marcus R Munafo and George Davey Smith, University of Bristol, School of Experimental Psychology.

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STUDY QUESTION How much weight do continually abstinent smokers gain during the first 12 months of quitting cigarette smoking?

SUMMARY ANSWER Smoking cessation is associated with a mean increase of 4-5 kg in body weight during the first 12 months of abstinence, with most weight gain occurring within three months.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Weight gain has been consistently associated with smoking cessation, although estimates of amounts have varied. Using data from smoking cessation clinical trials, this study lends support to weight gain after abstinence and shows a large variation in weight change, with 16% of quitters losing weight and 13% gaining more than 10 kg.

Selection criteria for studies

We searched the Central Register of Controlled Trials (CENTRAL) and trials listed as included in Cochrane reviews of smoking cessation interventions (that is, nicotine replacement therapy, nicotinic partial agonists, antidepressants, and exercise), for randomised trials of these interventions that reported weight change after cessation. In addition, we searched CENTRAL for trials of interventions designed to treat weight gain after cessation. We included trials if they recorded weight change from baseline to follow-up in abstinent smokers.

Primary outcome(s)

We calculated the mean (and 95% confidence intervals) of weight change from baseline to one, two, three, six, and 12 months after quitting using a random effects inverse variance model and the weighted mean of the standard deviations at each time point.

Main results and role of chance

We included 62 studies in the review. The table shows the estimates of weight gain after one, two, three, six, and 12 months of quitting using data from smoking cessation trial non-treatment comparison arms, which represented "untreated" smokers. Estimates were similar for smokers quitting who used nicotine replacement therapy, varenicline, or bupropion. With the means and weighted standard deviations, we calculated that at 12 months after cessation, 16%, 37%, 34%, and 13% of untreated quitters lost weight, and gained less than 5 kg, gained 5-10 kg, and gained more than 10 kg, respectively.

Bias, confounding, and other reasons for caution

Different studies and therefore different study participants contributed data to the meta-analyses at each time point, and we noted heterogeneity in most analyses. We therefore cannot interpret mean weight change across different time points as a trajectory. In addition, large weight gain might lead to intentional relapse to smoking, which would mean that participants who gain large amounts of weight early in their quit attempt and then relapse may not represented by our data.

Study funding/potential competing interests

We received no special funding for this research. H-JA has received sponsorship to attend scientific meetings, speaker honorariums, and consultancy fees from Pfizer, McNeil, GlaxoSmithKline, Pierre-Fabre Sante, Sanofi-Aventis, and Merck-Lipha; PA has done consultancy and research on behalf of the McNeil, Pfizer, and Celtic Biotechnology.

Weight change in untreated smokers, after continuous abstinence

Duration of abstinence	Mean (95% CI) change in weight (kg)*	Weighted mean standard deviation†	No of studies	I^2 (%)	No of participants
1 month	1.12 (0.76 to 1.47)	1.41	6	57	135
2 months	2.26 (1.98 to 2.54)	1.94	16	64	556
3 months	2.85 (2.42 to 3.28)	2.79	25	84	776
6 months	4.23 (3.69 to 4.77)	4.21	18	52	409
12 months	4.67 (3.96 to 5.38)	4.72	25	69	514

*Calculated from random effects meta-analysis, which assumes several different underlying true values for weight change, depending on population.
†Mean of standard deviations for each study contributing data to time point mean, weighted by number of participants contributing data to each mean. This value gives the standard deviation in weight gain for all participants within the study populations as a whole.

Risk of pneumonia associated with use of angiotensin converting enzyme inhibitors and angiotensin receptor blockers: systematic review and meta-analysis

Daniel Caldeira,[1] Joana Alarcão,[2] António Vaz-Carneiro,[2 3] João Costa[1 2 3]

EDITORIAL by Barnes

[1]Laboratory of Clinical Pharmacology and Therapeutics, Faculty of Medicine, University of Lisbon
[2]Center for Evidence-Based Medicine, Faculty of Medicine, University of Lisbon, Avenue Professor Egas Moniz, 1649-028, Lisbon, Portugal
[3]Cochrane Coordinating Center Portugal, Faculty of Medicine, University of Lisbon
Correspondence to: J Costa
jncosta@fm.ul.pt

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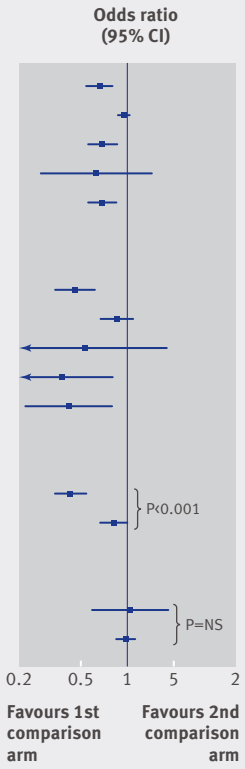
STUDY QUESTION Do angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) decrease the risk of pneumonia?

SUMMARY ANSWER ACE inhibitors, but not ARBs, may be important in reducing the risk of pneumonia. These data could discourage the withdrawal of ACE inhibitors in some patients with tolerable treatment related adverse events, namely cough, who are at particularly high risk of pneumonia.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

ACE inhibitors have secondary effects on the respiratory system, which may protect against pneumonia, although most of the data were provided by heterogeneous observational studies with inconclusive results. In pooled results from interventional and observational studies, ACE inhibitors had a significant protective role against pneumonia.

Summary of meta-analyses estimates and subgroup analyses



Selection criteria for studies

Potentially eligible studies were identified through a search of bibliographic databases from inception to June 2011 (Medline through PubMed and Web of Science with conference proceedings). We screened and cross checked identified systematic reviews and meta-analyses evaluating ACE inhibitors or ARBs, reference lists of identified papers, and the Food and Drug Administration website for regulatory documents with unpublished data from clinical trials. All participants were allowed irrespective of baseline diseases and risk factors. Studies had to evaluate ACE inhibitors or ARBs and placebo or other control groups. Eligible study designs were randomised controlled parallel trials and cohort and case-control studies.

Primary outcome

Incidence of pneumonia.

Main results and role of chance

Thirty seven studies were included. ACE inhibitors significantly reduced the risk of pneumonia compared with both control treatment (19 studies: odds ratio 0.66, 95% confidence intervals 0.55 to 0.80; I^2=79%) and ARBs (combined direct and indirect odds ratio estimate: 0.69, 0.56 to 0.85; I^2=0%).

Bias, confounding, and other reasons for caution

A key limitation of this review is that none of the randomised controlled trials were primarily designed to assess the effects of ACE inhibitors or ARBs in pneumonia. Although we searched a large number of studies, only a few reported this outcome. Observational studies had an important weight in the results for the primary outcome and this should be taken into account. We used adjusted indirect comparisons to estimate the effect of ACE inhibitors versus ARBs. Although there were no discrepancies with direct estimates, results should not be considered as definitive because of the possibility of imbalanced data from studies with different designs, patients' baseline risk, and length of follow-up, which are limitations to indirect comparisons.

Study funding/potential competing interests

This study was not funded by government or non-government grants. We have no competing interests.

Effectiveness of enhanced communication therapy in the first four months after stroke for aphasia and dysarthria: a randomised controlled trial

Audrey Bowen,[1] Anne Hesketh,[1] Emma Patchick,[1] Alys Young,[2] Linda Davies,[3] Andy Vail,[4] Andrew F Long,[5] Caroline Watkins,[6] Mo Wilkinson,[1] Gill Pearl,[7] Matthew A Lambon Ralph,[8] Pippa Tyrrell[9]

EDITORIAL by Rudd and Wolfe

[1]HCD, Ellen Wilkinson Building, University of Manchester MAHSC (Manchester Academic Health Science Centre), Manchester M13 9PL, UK
[2]Jean McFarlane Building, University of Manchester MAHSC, Manchester
[3]Health Sciences Research Group: Health Economics, Jean MacFarlane Building, University of Manchester MAHSC, Manchester
[4]University of Manchester MAHSC, R&D Support Unit, Clinical Sciences Building, Salford Royal NHS Foundation Trust, Salford M6 8HD
[5]School of Healthcare, University of Leeds, Leeds LS2 9UT
[6]Clinical Practice Research Unit, University of Central Lancashire, Preston PR1 2HE
[7]Speakeasy, c/o 2 Purbeck Drive, Bolton BL6 4JF
[8]NARU, Zochonis Building, University of Manchester MAHSC, Manchester
[9]University of Manchester MAHSC, Salford Royal NHS Foundation Trust, Salford
Correspondence to: A Bowen **audrey.bowen@manchester.ac.uk**

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STUDY QUESTION Is communication therapy in the first four months of stroke more effective than social contact alone in terms of the functional communicative ability of people with aphasia or dysarthria?

SUMMARY ANSWER No, communication therapy has no added benefit beyond that from natural recovery or social contact at six months.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Despite a firm consensus that speech and language therapy is beneficial after a stroke, clinical effectiveness remains unknown, cost effectiveness is untested within a trial, and service provision is highly variable and often poorly resourced. Although functional communication improved by six months there were no added benefits of contact with a qualified therapist (beyond initial assessment) in the first four months after stroke compared with a non-therapist.

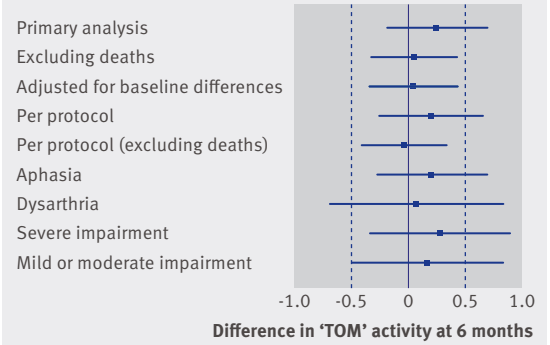
Design

This was an externally randomised, pragmatic, parallel, superiority trial with blinded outcome assessment. The intervention was enhanced, agreed best practice, communication therapy specific to aphasia or dysarthria, offered by speech and language therapists according to participants' needs for up to four months, with continuity from hospital to community. Comparison was with similarly resourced social contact (without communication therapy) from employed visitors. All participants had pre-randomisation assessment with a therapist.

Participants and setting

Participants were 170 adults (mean age 70 years) randomised within two weeks of admission to hospital with stroke (December 2006 to January 2010) whom speech and language therapists deemed eligible, and 135 carers. The setting was 12 UK hospital and community stroke services.

Sensitivity and subgroup analyses for the primary outcome (functional communicative ability at six months)



TOM = Therapy Outcome Measure

Primary outcome(s)

Primary outcome was blinded, functional communicative ability at six months on the Therapy Outcome Measure (TOM) activity subscale.

Main results and the role of chance

Both groups improved on the TOM activity subscale. The estimated six months group difference was not statistically significant, with 0.25 (95% CI −0.19 to 0.69) points in favour of therapy. There was no added benefit of therapy on secondary outcome measures, planned subgroup analyses (type of communication problem (aphasia or dysarthria) and severity), or serious adverse events.

Harms

Although not statistically significant, serious adverse events were less common after intervention (odds ratio 0.42 (95% CI 0.16 to 1.1)).

Bias, confounding, and other reasons for caution

Sensitivity analyses that adjusted for chance baseline imbalance further reduced the estimated six months group difference on the primary outcome. Per protocol analyses rejected a possible dilution of treatment effect from controls declining their allocation and receiving usual care. There was low power to detect differences in serious adverse events.

Generalisability to other populations

The sample had good external validity. Eligibility was determined by practising speech and language therapists. Those who consented were similar in measured characteristics to those who declined, with slightly less impairment in the latter. There was a good age range within this predictably older clinical population, most of whom had aphasia (alone or with dysarthria) and around half had dysphagia.

Study funding/potential competing interests

This project was funded by the NIHR Health Technology Assessment programme (project No 02/11/04) and the Stroke Association and is published in full in *Health Technology Assessment* 2012;16(26):1-160. The views and opinions expressed in this paper do not necessarily reflect those of the NIHR, Department of Health, or Stroke Association. There are no potential competing interests.

Trial registration number ISRCTN78617680.

Spironolactone and risk of incident breast cancer in women older than 55 years: retrospective, matched cohort study

Isla S Mackenzie,[1] Thomas M MacDonald,[1] Alastair Thompson,[2] Steve Morant,[1] Li Wei[1]

[1]Medicines Monitoring Unit (MEMO), University of Dundee, Dundee DD1 9SY, UK
[2]Dundee Cancer Centre, Dundee
Correspondence to: I S Mackenzie
i.s.mackenzie@dundee.ac.uk

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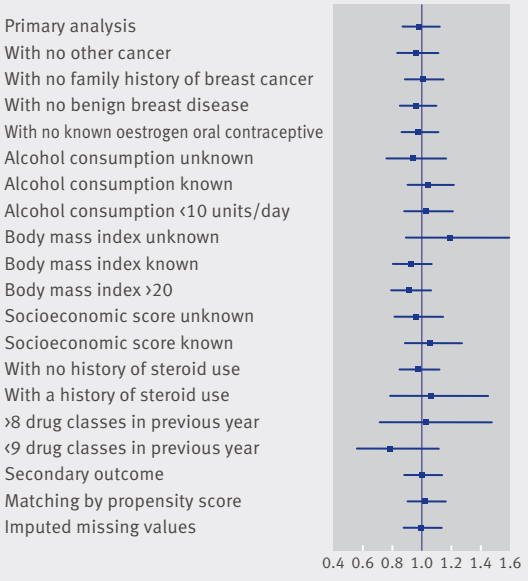
STUDY QUESTION Does spironolactone treatment increase the risk of new breast cancer in women aged over 55 years?

SUMMARY ANSWER Women older than 55 years with no history of the disease had no increase in risk of breast cancer after exposure to spironolactone treatment.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Spironolactone has hormonal effects on steroid receptors, and its use has increased greatly in recent years for conditions such as heart failure and resistant hypertension. We found no increased risk of breast cancer in women aged over 55 years with no history of breast cancer after exposure to spironolactone treatment.

Risk of breast cancer in exposed versus control cohorts



Participants and setting

We used the General Practice Research Database, a longitudinal database containing patient details from a representative sample of general practices in the United Kingdom. The study population included all women who contributed follow-up time to the database after the age of 55 years (8.4 million patient years, in which 29 491 incident cases of breast cancer occurred).

Design, size, and duration

Of 29 381 women who received at least two prescriptions for spironolactone after the age of 55 years, we excluded 1349 with a previous or undated history of breast cancer. A control cohort of 55 961 patients was constructed for the remaining 28 032 exposed patients, matched for practice, year of birth, and socioeconomic score (if available). The study compared time to the first diagnosis of breast cancer in the exposed and control cohorts, and adjusted for risk factors that were adequately recorded in the General Practice Research Database.

Main results and the role of chance

We found no association between exposure to spironolactone treatment and risk of breast cancer. In the primary analysis, the hazard ratio in the exposed cohort versus the control cohort was 0.99 (95% confidence interval 0.87 to 1.12). Significant risk factors included family history of breast cancer (3.87, 2.91 to 5.14), history of other cancers (1.64, 1.44 to 1.87), exposure to multiple drug classes (1.04 per additional class, 1.02 to 1.06), and exposure to steroids (0.78, 0.65 to 0.92).

Bias, confounding, and other reasons for caution

Some risk factors for breast cancer—for example, genetic abnormalities and age at menarche and menopause—were either unavailable or poorly recorded in the General Practice Research Database and we could not take account of them. Other entries were incompletely recorded and we carried out sensitivity analyses to assess any potential bias introduced. Inaccuracy of coding for the exposure, outcome, and risk factors may also be a limitation, but coding errors were probably similar in both cohorts. Although we found no link between incident breast cancer and spironolactone exposure, we did not look at other outcomes and therefore cannot comment on the general safety of spironolactone in women aged over 55 years.

Generalisability to other populations

Our results should be largely generalisable to the postmenopausal female population in the UK, but it is not known whether they would apply to younger women. The results are reassuring, in view of recent changes in guidelines on hypertension treatment from the National Institute for Health and Clinical Excellence, which will result in increased use of spironolactone in the UK.

Study funding/potential competing interests

No specific funding was received for this study. The study was sponsored by the University of Dundee. We declare no competing interests.

Cost effectiveness of vaccination against pandemic influenza in European countries: mathematical modelling analysis

Anna K Lugnér,[1] Michiel van Boven,[1] Robin de Vries,[2 3] Maarten J Postma,[2] Jacco Wallinga[1 4]

[1]Centre for Infectious Disease Control Netherlands, Epidemiology and Surveillance Unit, National Institute for Public Health and the Environment, PO Box 1, 3720 BA Bilthoven, Netherlands
[2]Department of Pharmacy, Unit of PharmacoEpidemiology and PharmacoEconomics, University of Groningen, Groningen, Netherlands
[3]Commercial Affairs, Roche Nederland, Woerden, Netherlands
[4]University Medical Center Utrecht, Julius Center for Health Sciences and Primary Care, Utrecht, Netherlands
Correspondence to: A Lugnér
anna.lugner@rivm.nl

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STUDY QUESTION What is the cost effectiveness of different vaccination strategies against influenza in four pandemic scenarios for Germany, the Netherlands, and the United Kingdom?

SUMMARY ANSWER As a rule, the most cost effective strategy was to prioritise vaccination of 5-19 year olds, with the exception of a scenario of no pre-existing immunity in elderly people and a vaccine available early in the pandemic. Under these circumstances, the optimal strategy differed between countries and was determined by the proportion of elderly people in the population.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS
Many countries have preparedness plans on how to prioritise vaccination against pandemic influenza if the vaccine supply falls short. Most countries have adapted their plans from other countries or from intergovernmental organisations. Our results show that general recommendations of a single strategy for a range of countries on how to prioritise pandemic influenza vaccination should be considered cautiously.

Main results
According to our analysis, no single vaccination strategy was most cost effective across countries. There are, however, some general rules. In most but not all scenarios, not vaccinating was the worst strategy and vaccinating 5-19 year olds (the high transmitter group) was the most cost effective strategy. Exceptions to this rule were when vaccine became available early in the pandemic and there was no pre-existing immunity in elderly people. For these exceptions, the most cost effective vaccination strategy might differ between countries. For example, in a scenario without pre-existing immunity and with an influenza vaccine becoming available early in the pandemic, vaccinating elderly people was the most cost effective strategy in Germany (€940 (£746, $1344) per QALY gained), whereas vaccinating high transmitters was the most cost effective strategy for the Netherlands (€525 per QALY gained) and the United Kingdom (€163 per QALY gained). The difference arises because of different demographic characteristics: Germany has a higher proportion of elderly people than the Netherlands and the United Kingdom.

Most cost effective vaccination strategy by country, when vaccines become available at start of the pandemic and there is no pre-existing immunity against the pandemic influenza strain in the population

Country	Best vaccination strategy
Germany	Vaccination of elderly people
Netherlands	Vaccination of high transmitters*
United Kingdom	Vaccination of high transmitters*

*Age group 5-19 years.

Design
A mathematical modelling analysis, combining a dynamic transmission model of influenza with a health economic model.

Sources of effectiveness
Cost effectiveness is calculated as the incremental cost per QALY gained, comparing vaccination with no vaccination, using direct costs only. Model variables were based on available data for the populations of Germany, the Netherlands, and the United Kingdom. The evaluated vaccination strategies were no vaccination, vaccination of the whole population, vaccination of elderly people, and vaccination of 5-19 year olds.

Data sources
Resource use and unit costs are based on literature, guidelines for economic evaluations, and expert opinion. The time horizon is one pandemic wave of several months.

Results of sensitivity analysis
In most of the sensitivity analyses, vaccinating high transmitters was the most cost effective option during a pandemic when there was pre-existing immunity in elderly people. If the transmissibility of the pandemic influenza strain was high and the vaccine became available at the peak of the pandemic, it would be more cost effective to vaccinate elderly people.

Limitations
When data were not available for all three countries, we used data from one country as a proxy. This resulted in a conservative comparison between countries.

Study funding/potential competing interests
This research was partly funded by a Quantitative Immunization and Vaccine-Related Research (QUIVER) grant from the World Health Organization. MJP has received unrestricted grants from Pfizer, GlaxoSmithKline, Sanofi Pasteur MSD, and MapiValues. Since completing this paper RdV has been employed by Roche Nederland.

Use of risk assessment instruments to predict violence and antisocial behaviour in 73 samples involving 24 827 people: systematic review and meta-analysis

Seena Fazel,[1] Jay P Singh,[2] Helen Doll,[3] Martin Grann[4]

[1]Department of Psychiatry, University of Oxford, Warneford Hospital, Oxford OX3 7JX, UK
[2]Department of Mental Health Law and Policy, University of South Florida, Tampa, FL, USA
[3]Department of Population Health and Primary Care, University of East Anglia, Norwich, UK
[4]Centre for Violence Prevention, Karolinska Institutet, Stockholm, Sweden
Correspondence to: S Fazel
seena.fazel@psych.ox.ac.uk

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Listen to a podcast interview with Seena Fazel at bmj.com/multimedia

STUDY QUESTION What is the predictive validity of commonly used instruments to assess risk of violent, sexual, and criminal behaviour and offending?

SUMMARY ANSWER These instruments appear to identify low risk individuals with high levels of accuracy, but their use as sole determinants of detention, sentencing, and release is not supported by the current evidence.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Structured risk assessment tools predict violent and antisocial behaviour more accurately than unstructured clinical assessments. However, structured instruments also produce high rates of false positive predictions, suggesting that caution is warranted when using such measures to influence decisions relating to individual liberty.

Selection criteria for studies

We searched PsycINFO, Embase, Medline, and United States National Criminal Justice Reference Service Abstracts between 1 January 1995 and 1 January 2011 to identify studies reporting on the predictive validity of commonly used risk assessment tools. Studies in all languages were considered for inclusion, as were unpublished reports. To be included in the meta-analysis, studies had to report rates of true and false positives and negatives at recommended cut-off scores for the outcome which the instrument was designed to predict.

Primary outcome(s)

Violent, sexual, and any criminal (violent or non-violent) behaviours and offences.

Main results and role of chance

Of 24 827 participants in 73 samples from 13 countries with collected information, 5879 (23.7%) offended over an average of 50 months. For risk assessment instruments predicting violent outcomes, the summary diagnostic odds ratio was 6.1 (95% confidence interval 4.6 to 8.1), and the median area under the curve was 0.72 (interquartile range 0.68-0.78). Of those participants who went on to violently offend, 92% (95% confidence interval 88% to 94%) had been classified as being at moderate or high risk of future violence (sensitivity). Of those who did not go on to violently offend, 36% (28-44%) had been judged to be at low risk (specificity). Of those predicted to violently offend, 41% did (interquartile range 27-60%; positive predictive value), which was equivalent to a median number needed to detain of 2 (2-4). Of those who were predicted not to violently offend, 91% did not (81-95%; negative predictive value), equivalent to a median number safely discharged of 10 (4-18). Positive predictive values were lower for tools developed to predict risk of sexual offending, and most accuracy estimates were lower for instruments predicting any offending. No evidence indicated that sex, ethnicity, age, type of instrument, temporal design, assessment setting, outcome location, length of follow-up, sample size, or publication status were associated with differences in predictive validity.

Bias, confounding, and other reasons for caution

We found moderate to high levels of heterogeneity between studies. We explored potential sources of heterogeneity using metaregression and subgroup analyses, and found no clear trends. Few samples reported on women; thus, this review was underpowered to examine whether predictive validity was different from men. We did not examine whether these instruments lead to interventions that improve clinical outcomes.

Study funding/potential competing interests

SF was funded by the Wellcome Trust. No competing interests declared.

Summary accuracy estimates produced by risk assessment tools for predicting outcomes

Accuracy estimate	Violent offending (n=30)	Sexual offending (n=20)	Criminal offending (n=23)
Diagnostic odds ratio (95% CI)	6.07 (4.58 to 8.05)	3.88 (2.36 to 6.40)	2.84 (2.09 to 3.88)
Sensitivity (95% CI)	0.92 (0.88 to 0.94)	0.88 (0.83 to 0.92)	0.41 (0.28 to 0.56)
Specificity (95% CI)	0.36 (0.28 to 0.44)	0.34 (0.20 to 0.51)	0.80 (0.67 to 0.89)
Area under the curve (IQR)	0.72 (0.68-0.78)	0.74 (0.66-0.77)	0.66 (0.58-0.67)
Positive predictive value (IQR)	0.41 (0.27-0.60)	0.23 (0.09-0.41)	0.52 (0.32-0.59)
Negative predictive value (IQR)	0.91 (0.81-0.95)	0.93 (0.82-0.98)	0.76 (0.61-0.84)
Number needed to detain (IQR)	2 (2-4)	5 (2-11)	2 (2-3)
Number safely discharged (IQR)	10 (4-18)	14 (5-48)	3 (2-6)

IQR=interquartile range; n=number of samples.