

SOVEREIGN/ISM/SPL

THIS WEEK'S RESEARCH QUESTIONS

- 320** How effective are two risk stratification schemes at predicting thromboembolic events in patients with atrial fibrillation?
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- 322** Has pay for performance in primary care improved the management and outcomes of hypertension in the UK?
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Predicting risk in patients with atrial fibrillation

Patients with atrial fibrillation have a substantial risk of stroke that is modified by the presence or absence of various risk factors. These factors have been used to develop risk stratification schemes that allow doctors to target those most in need of treatment. However, over the past 15-20 years, developments in risk schemes have not improved their predictive value for patients at high risk. For those deemed at "low risk" aspirin is the recommended treatment, but recent data suggest that this approach doesn't work for all patients in this stratum. Greater effort to identify "truly low risk" patients and to consider all others for oral anticoagulation is thought to be the way forward.

The most commonly used scheme for stratifying risk of stroke is the CHADS₂ score, while CHA₂DS₂-VASc was developed to complement CHADS₂, taking into account additional risk factors.

Jonas Bjerring Olesen and colleagues sought to validate these schemes in a large, real world cohort of patients with atrial fibrillation who had not received anticoagulation, using the Danish national patient registry (p 320). They found that CHA₂DS₂-VASc was better at predicting stroke in patients categorised as being at low and intermediate risk by the CHADS₂ scheme, so identifying patients at "truly low risk." The authors also estimated the importance of each component of the scores. In an editorial, Margaret Fang observes that although better risk schemes may help to inform choice of treatment, ultimately the decision should be based on the best balance of risk and benefit for the individual (p 289).

Pay for performance

Do financial incentives to improve the quality of healthcare really provide value for money? Brian Serumaga and colleagues looked at the effect of the UK pay for performance (PFP) initiative—the Quality and Outcomes Framework—on the management hypertension in primary care (p 322). Almost 20% of available PFP funds were directed at this goal.

A time series analysis of data for almost 500 000 patients between 2000 and 2007 showed no effect of pay for performance on the processes of care or on hypertension related clinical outcomes. However, there was some good news—a reason for the lack of effect seemed to be that care was already good or improving before the implementation of PFP in 2004. The specific targets for hypertension might have been set too low, meaning that doctors did not need to change behaviour greatly to attain them.

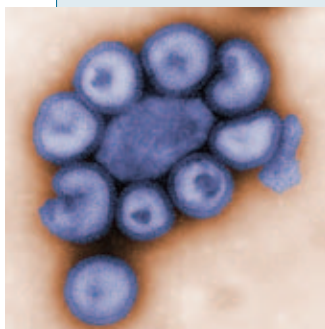
The authors say their findings emphasise the need for governments to test PFP schemes before they invest in them, and to investigate other methods of improving care, such as education. "It seems policy is heading in one direction, while the evidence is heading in another direction," said Serumaga, quoted in a *New York Times* blog about the paper (<http://nyti.ms/g9FsSI>).

In an editorial (p 291), John Reckless draws together lessons from this study and from this week's two Analysis articles (pp 313, 316), which also criticise aspects of cardiovascular disease prevention in the UK. His message: "The current model in the UK is not necessarily the right one or the only one."



SATURNSTILLS/SPL

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Effectiveness of AS03 adjuvanted pandemic H1N1 vaccine

Approval of vaccine produced to fight the influenza A/H1N1 pandemic in 2009 was accompanied in several countries by the expectation that the effectiveness of the vaccine would be assessed with post-marketing epidemiological methods. In a paper published on bmj.com this week, Danuta M Skowronski and colleagues report estimates of the effectiveness of the AS03 adjuvanted pandemic H1N1 vaccine most used in Canada during the autumn of 2009, based on Canada's well established sentinel surveillance system and using a case-control design (doi:10.1136/bmj.c7297). They found that a single dose of the vaccine conferred excellent protection; 14 days or more after vaccination, its estimated effectiveness was 93% (95% confidence interval 69% to 98%) against medically attended, laboratory confirmed influenza A/H1N1 illness. This finding primarily reflected protection conferred to children and young adults. An intriguing and as yet unanswered question is how much the vaccine given at the end of 2009 or in early 2010 has continued to protect against the H1N1 virus in the 2010-11 season, say editorialists John Watson and Richard Pebody (doi: 10.1136/bmj.d545).

Validation of risk stratification schemes for predicting stroke and thromboembolism in patients with atrial fibrillation: nationwide cohort study

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EDITORIAL by Fang

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STUDY QUESTION

In predicting thromboembolic events in patients with atrial fibrillation, what is the effect of the individual risk factors of CHADS₂ and CHA₂DS₂-VASc, and which of the two risk stratification schemes has the best predictive ability?

SUMMARY ANSWER

The risk associated with a specific risk stratification score depended on the risk factors composing the score; CHA₂DS₂-VASc performed better than CHADS₂ in predicting patients at high risk, and those categorised as being at low risk using CHA₂DS₂-VASc were at truly low risk of thromboembolism.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The most commonly used risk stratification scheme is CHADS₂; CHA₂DS₂-VASc was developed to complement CHADS₂ by considering additional thromboembolic risk modifiers. Use of CHA₂DS₂-VASc significantly improved thromboembolic risk stratification in patients with non-valvular atrial fibrillation.

Participants and setting

We included all Danish patients admitted to hospital with non-valvular atrial fibrillation and not receiving vitamin K antagonists.

Design, size, and duration

This was a registry based cohort study of 73 538 patients admitted to hospital with non-valvular atrial fibrillation in the period 1997-2006. We used the CHADS₂ (Congestive heart failure, Hypertension, Age ≥75 years, Diabetes, previous Stroke) and CHA₂DS₂-VASc (CHA₂DS₂-Vascular disease, Age 65-74 years, Sex category) risk stratification schemes to categorise patients as being at low, intermediate, or high risk of thromboembolism. The primary study end point was hospital admission or death due to thromboembolism.

Main results and the role of chance

In patients at "low risk" (score=0), the rate of thromboembolism per 100 person years was 1.67 (95% confidence interval 1.47 to 1.89) with CHADS₂ and 0.78 (0.58 to 1.04) with CHA₂DS₂-VASc, at one year follow-up. In patients at "intermediate risk" (score=1), this rate was 4.75 (4.45 to

5.07) with CHADS₂ and 2.01 (1.70 to 2.36) with CHA₂DS₂-VASc. The risk associated with CHADS₂ score=1 depended on the specific conditions (risk factors) composing the score; the risk factor associated with the highest risk was age ≥75 (hazard ratio 3.52, 3.05 to 4.07), whereas hypertension was associated with the lowest thromboembolic risk (hazard ratio 1.45, 1.17 to 1.79). For patients with CHA₂DS₂-VASc score=1, diabetes was associated with the highest thromboembolic rate (hazard ratio 3.47, 1.65 to 7.27) and age 65-74 had the second highest rate (hazard ratio 2.88, 2.29 to 3.62). The table shows the predictive ability of the two schemes.

Bias, confounding, and other reasons for caution

We had no information on the reason(s) for absence of vitamin K antagonist treatment in this specific cohort of patients with non-valvular atrial fibrillation. Retrospective studies may be affected by misclassification and inclusion bias.

Generalisability to other populations

The study used data from complete nationwide registries, so no selection bias existed in terms of factors such as socioeconomic status. However, we included only patients admitted to hospital, who will often have a higher risk of thromboembolic events and death than the average patient seen by general practitioners.

Study funding/potential competing interests

This study did not receive any funding.

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C STATISTICS (95% CI) FOR CATEGORISING PATIENTS AS BEING AT LOW, INTERMEDIATE, OR HIGH RISK OF THROMBOEMBOLISM

Risk stratification scheme	1 year follow-up	5 year follow-up	10 year follow-up
CHADS ₂	0.722 (0.694 to 0.748)	0.796 (0.778 to 0.812)	0.812 (0.796 to 0.827)
CHA ₂ DS ₂ -VASc	0.850 (0.829 to 0.871)	0.880 (0.866 to 0.893)	0.888 (0.875 to 0.900)

Based on Cox regression models with covariates analysed as categorical variables.

Outcomes of chest compression only CPR versus conventional CPR conducted by lay people in patients with out of hospital cardiopulmonary arrest witnessed by bystanders: nationwide population based observational study

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STUDY QUESTION

Is cardiopulmonary resuscitation (CPR) with chest compression only as good as or better than conventional CPR for people who have a cardiopulmonary arrest out of hospital?

SUMMARY ANSWER

Conventional CPR was associated with better outcomes than chest compression only CPR for selected cases of out of hospital cardiopulmonary arrest, such as those whose arrest was of non-cardiac origin and younger people, and for people in whom there was a delay before CPR was started.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Chest compression only CPR has become popular for bystander resuscitation but its effectiveness compared with conventional CPR in patients who experience out of hospital cardiopulmonary arrest is still controversial. In this study conventional CPR was associated with better outcomes than chest compression only CPR in terms of one month survival and neurologically favourable one month survival.

Participants and setting

The setting was the nationwide emergency medical service system in Japan. Participants included all consecutive patients who experienced an out of hospital cardiopulmonary arrest, January 2005 to December 2007, that was witnessed at the moment of collapse.

Design

A nationwide population based observational study.

Primary outcomes

Rates of one month survival and neurologically favourable one month survival defined as category one (good cerebral performance) or two (moderate cerebral disability) of the cerebral performance categories.

Main results and the role of chance

Conventional CPR was associated with better outcomes than

chest compression only CPR, for both one month survival (adjusted odds ratio 1.17, 95% confidence interval 1.06 to 1.29) and neurologically favourable one month survival (1.17, 1.01 to 1.35). Neurologically favourable one month survival decreased with increasing age and with delays of up to 10 minutes in starting CPR for both methods of CPR. The benefit of conventional CPR over chest compression only CPR was significantly greater at younger ages for non-cardiac cases ($P=0.025$), and this benefit was also significantly increased with a delay to the start of CPR after the arrest was witnessed for non-cardiac cases ($P=0.015$) and all cases combined ($P=0.037$).

Bias, confounding, and other reasons for caution

There was a risk of lower accuracy and more unpredicted confounding factors for the analysis of patients aged under 40 because lower age ranges had many fewer cases. The timing of the out of hospital cardiopulmonary arrest might have been inaccurate because it would have been difficult for witnesses to recognise the exact time in such an emergency situation. The selection of confounding factors needs to be considered further. Information on the quality of bystander CPR was not available in the database. The results of the overall analysis showed significance, but the difference between the two groups was not large (odds ratio 1.21, adjusted odds ratio 1.17, for one month survival). Thus, there was a potential risk of a type 1 error. The outcome measures could be determined better for a longer period of observation. Within the present database, however, the only outcome measures available were rates of neurologically favourable one month survival and one month survival.

Generalisability to other populations

As data were derived from a national database of all patients who experienced out of hospital cardiopulmonary arrest in Japan, generalisability to other ethnicities remains unclear.

Study funding/potential competing interests

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

OUTCOMES IN PEOPLE WHO RECEIVED CPR FROM LAY PERSON AFTER OUT OF HOSPITAL CARDIOPULMONARY ARREST WITNESSED BY BYSTANDER

	Chest compression only CPR	Conventional CPR	Odds ratio (95% CI), P value	
			Unadjusted	Adjusted*
One month survival	8.7% (1799/20 707)	10.3% (1997/19 327)	1.21 (1.13 to 1.29), <0.001	1.17 (1.06 to 1.29), 0.002
Neurologically favourable one month survival	4.6% (943/20 662)	5.6% (1070/19 247)	1.23 (1.12 to 1.35), <0.001	1.17 (1.01 to 1.35), 0.037

*Adjusted for age, sex, assistance from dispatcher, initial identified cardiac rhythm, cause of cardiac arrest, relation of bystander to patient, use of public access automated external defibrillator, first shock from emergency medical staff, use of a drug during CPR, and duration between bystander witnessing event to bystander starting CPR, to CPR by emergency medical staff, and to patient's arrival at hospital.

Effect of pay for performance on the management and outcomes of hypertension in the United Kingdom: interrupted time series study

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EDITORIAL by Reckless
ANALYSIS pp 313, 316

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STUDY QUESTION

Has pay for performance in primary care improved the management and outcomes of hypertension in the United Kingdom?

SUMMARY ANSWER

Against a background of continuous improvement, pay for performance had no effect on processes of care and major outcomes for patients with hypertension in the United Kingdom.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

There is scant evidence from sufficiently large, well controlled studies to support or disprove pay for performance as an effective tool to drive improvements in healthcare, even for common conditions such as hypertension. The Quality and Outcomes Framework (primary care pay for performance initiative) in the United Kingdom did not have any effect on hypertension care and outcomes probably because performance targets were set too close to existing practice.

Design, participants, and setting

We used a strong interrupted time series design to study the effect of the pay for performance initiative (started in April 2004) on 470 725 primary care patients with hypertension diagnosed between January 2000 and August 2007 using data extracted from The Health Improvement Network (THIN).

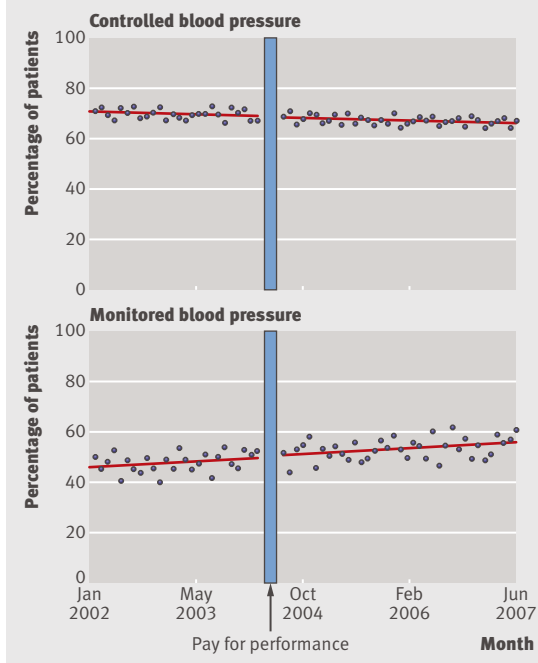
Primary outcomes

Controlling for pre-existing secular trends, we examined centiles of systolic and diastolic blood pressures over time, rates of blood pressure monitoring, blood pressure control, and treatment intensity at monthly intervals for baseline (48 months) and 36 months after the implementation of pay for performance. We also examined the cumulative incidence of major hypertension related outcomes and all cause mortality for subgroups of newly treated and treatment established patients to study the effect on patients at different stages of the condition.

Main results and the role of chance

After accounting for secular trends, we found no changes in blood pressure monitoring (level change $P=0.669$ and trend change $P=0.615$), control (level change $P=0.109$ and trend change $P=0.569$), or treatment intensity (level change $P=0.412$ and trend change $P=0.706$) attributable to the pay for performance initiative. We did not find any effect of the initiative on the cumulative incidence of stroke, myocardial infarction, renal failure, heart failure, or all cause mortality in both treatment experienced and newly treated subgroups.

EFFECT OF PAY FOR PERFORMANCE ON BLOOD PRESSURE CONTROL AND MONITORING IN UNITED KINGDOM



Bias, confounding, and other reasons for caution

We designated April to June 2004 as the intervention period to control for potential co-intervention confounding from the June 2004 NICE hypertension guidelines.

Generalisability to other populations

Overall, 99.6% of general practitioners participated in the initiative within its first year of inception. We also used a large primary care population, which is representative of where most patients in the United Kingdom are assessed. Our study has good external validity.

Study funding/potential competing interests

This research received no specific grant from any funding agency in the public, commercial or not for profit sectors. BS is supported by a fellowship in pharmaceutical policy research at Harvard Medical School. DRD, FZ, and SBS are investigators in the HMO Research Network Centre for Education and Research in Therapeutics and are supported by the Agency for Healthcare Research and Quality. SM receives salary support (health scholar) from the Alberta heritage foundation for medical research. All authors have no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years.

Impact of a statewide intensive care unit quality improvement initiative on hospital mortality and length of stay: retrospective comparative analysis

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STUDY QUESTION

What is the impact of implementing the Michigan Keystone ICU (intensive care unit) project, a comprehensive statewide quality improvement initiative focused on reduction of infections, on hospital mortality and length of stay for adults aged 65 or more admitted to intensive care units?

SUMMARY ANSWER

The project was associated with a significant decrease in hospital mortality in the state of Michigan compared with the surrounding Midwest region. The study was not, however, sufficiently powered to show a significant difference in length of stay.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Quality improvement initiatives have shown reductions in hospital acquired infections, but their impact on other important outcomes is poorly understood. This study found a significant reduction in hospital mortality for Medicare patients in the intensive care unit after the implementation of a comprehensive statewide initiative.

Participants and setting

The study sample included all hospital admissions for adults aged 65 or more treated in any intensive care unit in Michigan (95 hospitals; 238 937 admissions) versus comparison hospitals in the Midwest region of the United States (364 hospitals; 1 091 547 admissions).

Design, size, and duration

We carried out a retrospective comparative study, using data from Medicare claims, to evaluate the impact of the initiative on hospital mortality and length of stay. The study period (October 2001 to December 2006) spanned two years before the project was initiated to 22 months after its implementation.

Main results and the role of chance

The overall trajectory of mortality outcomes differed significantly between the study and comparison groups upon

implementation of the project ($P=0.033$). Reductions in mortality compared with baseline were significantly greater for patients in the study group versus comparison group during post-implementation months 1-12 and 13-22. The overall trajectory of length of stay did not differ significantly between groups upon implementation of the project ($P=0.560$). Differences in adjusted length of stay compared with baseline did not reach statistical significance between the groups during implementation of the project and during post-implementation months 1-12 and 13-22.

Bias, confounding, and other reasons for caution

Given the non-randomised study design, other subsequent efforts for improvement in Michigan, and potential differential trends in discharge practices between groups, findings cannot be definitively attributed to this project. However, no other known large scale initiatives were introduced across Michigan during implementation of the project, and a large and representative comparison group was included to account for temporal trends in patient outcomes.

Generalisability to other populations

Generalisability of the findings may be limited to patients aged 65 or more; however, these patients represent about half of all patients admitted to intensive care units in the United States.

Study funding/potential competing interests

This study was carried out as part of AL-S's PhD dissertation at the Johns Hopkins Bloomberg School of Public Health. PJP has received grants from the Agency for Healthcare Research and Quality, the National Patient Safety Agency, and private philanthropy to implement the Michigan programme in all 50 states in the United States and to measure and improve patient safety, receiving speaking honorariums and expenses for travel and accommodation from hospitals and healthcare systems, providing expert testimony to the US Congress, receiving royalties from sales of the book *Safe Patients, Smart Hospitals*, and receiving payment for development of education presentations from Leigh Bureau on quality and safety.

ADJUSTED ODDS RATIOS FOR MORTALITY IN MICHIGAN HOSPITALS AND COMPARISON HOSPITALS

Study period* (Oct 2001 to Dec 2006)	Adjusted odds ratio (95% CI)	
	Study group	Comparison group
Pre-implementation (12 months)	0.98 (0.94 to 1.01)	0.96 (0.95 to 0.98)
Project initiation (5 months)	0.97 (0.92 to 1.01)	0.97 (0.94 to 0.99)
Implementation (12 months)	0.89 (0.86 to 0.93)	0.91 (0.89 to 0.93)
Post-implementation:		
1-12 months (12 months)	0.83 (0.79 to 0.87)	0.88 (0.85 to 0.90)
3-22 months (10 months)	0.76 (0.72 to 0.81)	0.84 (0.81 to 0.86)

Wald test for global differences in trajectory of mortality upon implementation of project (interaction terms for group by implementation and two post-implementation periods): $P=0.033$.

*Study period includes 12 month baseline period before pre-implementation.

Portrayal of caesarean section in Brazilian women's magazines: 20 year review

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STUDY QUESTION

What is the quality, accuracy, and comprehensiveness of the information provided on caesarean section in Brazilian women's magazines?

SUMMARY ANSWER

Most articles published in Brazilian women's magazines do not use optimal sources of information; the portrayal of caesarean section presented is mostly balanced, not explicitly in favour of one or another route of delivery, but incomplete.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Caesarean section rates are increasing worldwide, and the reasons remain unclear. The portrayal of caesarean section in women's magazines in Brazil is incomplete and may be leading women to underestimate important maternal and perinatal risks associated with this route of delivery.

Selection criteria for studies

We identified women's magazines with the largest distribution in Brazil between 1988 and 2008 through the official national media indexing organisations. We hand searched issues and photocopied articles that provided information on caesarean section for reading of the full text. Articles with objective information or advice, comments, opinions, or the experience of ordinary women or celebrities on delivery by caesarean section were eligible. We created a content analysis abstraction form, and two reviewers extracted information.

Primary outcome(s)

The main outcomes were sources of information mentioned by the author of the article, the accuracy and completeness of data presented on caesarean section, and alleged reasons why women would prefer to deliver through caesarean section.

Main results and role of chance

We included 118 articles. The main cited sources of information were health professionals (78% of the articles, n=92). Information provided on caesarean section was not comprehensive in many aspects and did not provide important facts that could help readers to understand better the risks and benefits of delivering by caesarean section. The benefits most often attributed to delivery by caesarean section were reduction of pain and convenience for family or health professionals. Less than 20% of the articles mentioned cost factors or the need for longer hospital stays for women having a caesarean section. Although more than 80% (n=97) of the articles presented at least one short term risk or inconvenience associated with caesarean section, these were mostly related to social aspects or relatively innocuous outcomes,

REASONS WHY WOMEN WOULD REQUEST ELECTIVE* CAESAREAN SECTION ACCORDING TO BRAZILIAN WOMEN'S MAGAZINES, 1988-2008

	Articles (n=118)
Reasons for antepartum elective caesarean section	
No reasons mentioned	63 (53)
Articles that give reasons for elective caesarean section:	55 (47)
To avoid labour pain	37 (31)
For convenience of family	20 (17)
Fear of vaginal delivery	11 (9)
To avoid surprises and rushing; to control things	7 (6)
For medical convenience	4 (3)
Reasons for intrapartum elective caesarean section	
No reason mentioned	111 (94)
Reason: pain, fatigue, despair	7 (6)
Values are numbers (percentages). *Without a medical indication.	

such as increased recovery time at home. Much more important immediate risks related to caesarean section, such as increased mortality, infection, haemorrhage, or urinary or intestinal injuries were completely ignored by more than 70% of the articles. Only a third of the articles mentioned any long term maternal risks or perinatal complications potentially associated with caesarean section. Fear of pain was the main reported reason why women would prefer to deliver by caesarean section.

Bias, confounding, and other reasons for caution

We acknowledge the fact that some degree of subjectivity in assessing the scientific quality of health related articles in the press is inevitable. No uniform, comprehensive, and internationally accepted standards and assessment tools are available to critically appraise this type of literature. This study could not and did not intend to evaluate the effect of Brazilian women's magazines in shaping their readers' opinion or whether they actually influenced women's decisions on route of delivery. Furthermore, we acknowledge that women's magazine articles are not the only source of information that could influence the opinion of women on the choice of vaginal delivery or caesarean section. These results reflect the information presented in Brazilian women's magazines. This study is part of a larger multi-country investigation covering women's magazines from countries in Europe, Latin America, and North America, where rates of caesarean section are increasing in an unprecedented manner.

Study funding/potential competing interests

None.

bmj.com/archive

- Brazil puts emergency medical plan into action (*BMJ* 2011;342:d359)
- Brazil's Family Health Programme (*BMJ* 2010;341:c4945)
- Health equity in Brazil (*BMJ* 2010;341:c6542)
- Economic success threatens aspirations of Brazil's public health system (*BMJ* 2010;341:c5453)