RESEARCH

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THIS WEEK'S RESEARCH QUESTIONS

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Is glucose self monitoring worth it?

JOHNTHYS/SPL

Blood glucose monitoring in diabetes is useful for detecting hypoglycaemia and hyperglycaemia, allowing patients to adjust their insulin or behaviour, according to national guidelines, patient advice leaflets, and the *British National Formulary*.

But for many people with type 2 diabetes who do not use insulin and for whom the risk of hypoglycaemia is low, is testing worth it? If not, this is useful information; it is not only unpleasant to self test but also expensive. Although the testing devices themselves are relatively inexpensive, test strips typically start at £15 for 50 strips.

Previous systematic reviews have produced varied estimates on the utility of testing, Andrew Farmer and colleagues write in the introduction to their systematic review and meta-analysis (p 14). To try and get a clearer answer, they excluded small trials and those of short duration. They also found new trials, used individual level data, and examined the possibility that specific groups of patients, such as those with poorer control, might benefit more than others.

The headline result is that, with self monitoring, HbA_{1c} was reduced by 0.25% at six months. A 0.5% reduction in HbA_{1c} is often considered clinically significant in drug trials. There was no specific group of patients who benefited particularly. The authors are unconvinced that monitoring is worth it, but do not rule out the possibility that future trials might challenge this if monitoring results were to drive greater behavioural change.

Combating non-communicable diseases in developing countries

Last year's special session of the UN General Assembly on health met to discuss the rising burden of non-communicable diseases, especially in developing countries, and how to integrate them into future development activities (*BMJ* 2011;343:d6034). But among the myriad of diseases and injuries, which should be prioritised and what methods used to combat them? A key consideration must be cost effectiveness, and this week we have published online a series of cost effectiveness analyses of over 500 single or combined interventions for the prevention and control of non-communicable diseases and injuries in countries in sub-Saharan Africa and South East Asia that have high adult and child mortality.

The series contains six papers on major disease areas or clusters—cardiovascular disease, diabetes, and tobacco use (Mónica Ortegón and colleagues, doi:10.1136/bmj.e607), chronic respiratory diseases (Anderson Stanciole and colleagues, doi:10.1136/bmj.e608), cancer (Gary Ginsberg and colleagues, doi:10.1136/bmj.e614), sensory loss disorders (Rob Baltussen and Andrew Smith, doi:10.1136/bmj.e615), mental disorders (Dan Chisholm and Shekhar Saxena, doi:10.1136/bmj.e609), and road traffic injury (Chisholm and colleagues, doi:10.1136/bmj.e612). A companion paper uses the same methods—based on the WHO's Choosing Interventions that are Cost-Effective (CHOICE) programme—to investigate the burden of these conditions at the country level (Mexico) as opposed to the regional level (Joshua Salomon and colleagues, doi:10.1136/bmj.e355).

In the print journal we publish an accompanying analysis by Dan Chisholm and colleagues (p 26) which draws together the findings to identify those strategies that offer best value for money in the low income regions.

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

SPL

Incidence of diabetic retinopathy in people with type 2 diabetes mellitus attending the Diabetic Retinopathy Screening Service for Wales This retrospective analysis by R L Thomas and colleagues supports the extension of the screening interval for people with type 2 diabetes beyond the currently recommended 12 months, with the possible exception of those who have had diabetes for 10 years or more and take insulin treatment (doi:10.1136/bmj.e874).

Cardiovascular disease in kidney donors This matched cohort study by Amit Garg and colleagues found that in the first decade after kidney donation the risk of major cardiovascular events in Canadian donors was no higher than in a similarly healthy segment of the general population, supporting the safety of the practice among carefully selected donors (doi:10.1136/bmj.e1203).

Screening and cervical cancer cure This population based cohort study by Bengt Andrae and colleagues found that in Sweden cervical screening is associated with improved cure of cervical cancer, and this improvement was not attributable to lead time bias (doi:10.1136/bmj.e900).

Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes

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bmj.com/diabetes
Diabetes resource from BMJ Group

STUDY QUESTION How effective is the routine use of self monitoring of blood glucose (SMBG) compared with clinical management without SMBG for improving glycaemic control in people with non-insulin treated type 2 diabetes?

SUMMARY ANSWER SMBG levels compared with no self monitoring resulted in small but statistically significant reductions in HbA_{1c} level at six months, also at three and 12 months. The mean pooled reduction in HbA_{1c} levels across the trials was 9.6 mmol/mol (0.88%) in the SMBG group and 7.5 mmol/mol (0.69%) in the control group. No change was observed for older and younger people and those with a HbA_{1c} level above 86 mmol/mol (10%), and confidence intervals were wide, but otherwise a consistent effect of a small reduction in levels was observed in other prespecified patient subgroups.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS No trial has been large enough to identify the characteristics of people with non-insulin treated type 2 diabetes who might benefit most from SMBG levels. Evidence from meta-analysis of individual patient data was not convincing to support routine use of SMBG in people with non-insulin treated type 2 diabetes, or suggest a greater effect of SMBG in patients with a baseline HbA_{1c} level above 8%.

Selection criteria for studies

We searched Medline, Embase, a high quality systematic review of trials on SMBG, conference proceedings, and abstracts, and approached chief investigators of trials published since 2000. Randomised controlled trials had to compare an intervention of SMBG in people with non-insulin treated type 2 diabetes with clinical management without SMBG and assess glycaemic control.

Primary outcomes

Difference in change in HbA_{1c} levels between the SMBG and non-SMBG groups.

Main results and the role of chance

2552 patients were randomised in the six included trials. At six months the mean reduction in HbA_{1c} level in the SMGB group compared with the no self monitoring group was −2.7 mmol/mol (95% confidence interval −3.9 to −1.6, 0.25%). The mean reduction in levels between groups was 2.0 mmol/mol (3.2 to 0.8, 0.25%) at three months (five trials) and 2.5 mmol/mol (4.1 to 0.9, 0.35%) at 12 months (three trials). The difference in levels between groups was consistent across baseline level, age, sex, and duration of diabetes, although the numbers of older and younger people and those with HbA_{1c} levels >86 mmol/mol (10%) were insufficient for interpretation. Systolic blood pressure (−0.2 mm Hg, 95% confidence interval −1.4 to 1.0), diastolic blood pressure (−0.1 mm Hg, −0.9 to 0.6), and total cholesterol level (−0.1 mol/L, 95% confidence interval −0.2 to 0.1) did not change.

Bias, confounding, and other reasons for caution

Use of a prespecified statistical analysis plan for all studies limited bias from pooling summary data from investigators. As outcomes between trials showed no heterogeneity we did not include further analysis of differences between populations and interventions. Data about socioeconomic groupings and changes to treatment were insufficient to explore their impact on outcomes.

Study funding/potential competing interests

AJF, RP, AW, JO, and CH are members of the National Institute for Health Research (NIHR) School of Primary Care. AJF receives support from the NIHR Oxford Biomedical Research Centre. This work was supported by the NIHR Health Technology Assessment Programme (018/0004). AHB has received lecture fees and advisory payments from LifeScan Scotland and Roche. The opinions expressed in this paper are not necessarily those of the Department of Health, UK.

Changes in outcomes from baseline between participants allocated to self monitoring of blood glucose (SMBG) levels or no self monitoring

Outcomes	No of trials	No in SMBG group/ No in control group	Adjusted estimate* (95% CI)	Adjusted P value
Primary outcome: HbA_{1c} level (mmol/mol) at 6 months	6	1054/881	−2.7 (−3.9 to −1.6)	<0.001
Secondary outcomes				
HbA_{1c} level (mmol/mol):				
3 months	5	845/692	−2.0 (−3.2 to −0.9)	0.001
12 months	3	436/292	−2.5 (−4.1 to −0.9)	0.002
Blood pressure (mm Hg):				
Systolic	3	876/732	−0.16 (−1.37 to 1.05)	0.79
Diastolic	3	875/732	−0.15 (−0.87 to 0.58)	0.69
Total cholesterol level (mmol/L)	3	355/290	−0.06 (−0.19 to 0.07)	0.38

*Effect after adjustment for age, sex, and duration of diabetes and baseline outcome measure, with trial and intervention coefficients as random effects.

Group art therapy as an adjunctive treatment for people with schizophrenia: multicentre pragmatic randomised trial

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STUDY QUESTION

Does referring people with schizophrenia to group art therapy improve global functioning and mental health?

SUMMARY ANSWER

Referring people with schizophrenia to group art therapy as delivered in this trial did not improve global functioning or symptoms of schizophrenia.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

When people with established schizophrenia are referred to group art therapy, many do not attend. Even among those that do, improvements in symptoms of schizophrenia and social functioning are unlikely.

Design

A single blind, parallel group, randomised controlled trial of referral to group art therapy plus standard care, activity group plus standard care, or standard care alone. Participants were randomised through an independent and remote telephone service using permuted blocks, stratified by site. Groups were run on a weekly basis for 12 months. In art therapy, people were given access to a range of art materials and encouraged to use these to express themselves freely. Members of activity groups were offered various activities that did not involve use of art or craft materials and were encouraged to collectively select those they wanted to pursue.

Participants and setting

In four centres in England and Northern Ireland we identified people aged 18 or over with a diagnosis of schizophrenia who were willing to take part in group therapy and could provide written informed consent to take part in the trial. We excluded those with severe cognitive impairment, those unable to speak sufficient English to complete the baseline assessment, and those already attending art or other creative therapies.

Primary outcomes

Global functioning (global assessment of functioning scale) and symptoms of schizophrenia (positive and negative syndrome scale) measured 12 and 24 months after randomisation.

Main results and the role of chance

417 participants were assigned to art therapy (n=140), activity groups (n=140), or standard care alone (n=137). Primary outcomes did not differ between the three study arms. At 24 months the adjusted mean difference between art therapy and standard care on the global assessment of functioning scale was −0.9 (95% confidence interval −3.8 to 2.1), and on the positive and negative syndrome scale was 0.7 (−3.1 to 4.6). Analysis of the instrumental variables indicated that attendance at art therapy was not associated with improvements in these outcomes.

Harms

No harms were identified.

Bias, confounding, and other reasons for caution

Low levels of attendance limited opportunities for group interaction and may have had an impact on the effectiveness of this group based intervention.

Generalisability to other populations

These results are generalisable to people with established schizophrenia in other community settings. We did not examine the impact of art therapy for people treated on inpatient units or those with other types of mental disorder.

Study funding/potential competing interests

This study was supported by the National Institute of Health Research Technology Assessment Programme.

Trial registration number

Current Controlled Trials ISRCTN46150447.

Main outcomes at baseline and 12 and 24 months. Values are means (SDs)

	Standard care			Activity groups			Group art therapy		
Outcome measure	Baseline (n=137)	12 months (n=121)	24 months (n=117)	Baseline (n=140)	12 months (n=121)	24 months (n=121)	Baseline (n=140)	12 months (n=119)	24 months (n=117)
Global assessment of functioning (n=355)	44.9 (12.6)	45.7 (14.4)	46.8 (12.8)	45.0 (12.7)	45.5 (14.1)	46.4 (13.6)	44.8 (13.1)	44.9 (14.6)	45.6 (13.1)
Positive and negative syndrome scale total score (n=348)	72.6 (21.5)	71.2 (24.6)	68.1 (20.7)	75.3 (22.0)	69.6 (23.2)	66.9 (23.3)	74.3 (23.7)	72.7 (27.3)	69.2 (21.8)

CME

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Influence of definition based versus pragmatic birth registration on international comparisons of perinatal and infant mortality: population based retrospective study

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STUDY QUESTION

What effect do variations in the registration of extremely low birthweight and early gestation births have on perinatal and infant mortality rankings of industrialised countries?

SUMMARY ANSWER

International differences in reported rates of extremely low birthweight and very early gestation births probably reflect variations in birth registration and compromise the validity of international rankings of perinatal and infant mortality.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

International rankings of countries based on perinatal, infant, or child mortality are a cause of debate in industrialised countries. Substantial differences exist in reported rates of extremely low birthweight and very early gestation births in industrialised countries, and such differences compromise the validity of international rankings based on perinatal, infant, or child mortality.

Participants and setting

We used national data on live births and fetal, neonatal, and infant deaths from Australia, Canada, European countries, and the United States for 2004 and from Australia, Canada, and New Zealand for 2007.

Design

This was a retrospective population based study.

Primary outcomes

The main outcomes were reported proportions of live births with birth weight less than 500 g or 1000 g or gestational age of less than 24 or 28 weeks; crude rates of fetal, neonatal, and infant mortality; and mortality rates calculated after exclusion of births below 500 g or 1000 g birth weight or at less than 24 or 28 weeks' gestational age.

Main results and the role of chance

The proportion of live births with birth weight below 500 g varied widely from less than 1 per 10 000 live births in Belgium and Ireland to 10.8 in Canada and 16.9 per 10 000 live births in the United States. Neonatal deaths below 500 g, as a proportion of all neonatal deaths, also ranged from less than 1% in countries such as Luxembourg and Malta to 29.6% in Canada and 31.1% in the United States. Rankings of countries based on crude fetal, neonatal, and infant mortality rates differed substantially from rankings based on rates calculated after exclusion of births with a birth weight below 1000 g. For instance, Canada was placed 18th and the United States 22nd on the basis of crude neonatal mortality rates. When neonatal mortality rates were calculated after exclusion of live births below 1000 g, Canadian and US ranks improved substantially to 12th and 11th place. Of the 10 countries that ranked ahead of the United States in neonatal mortality excluding live births below 1000 g, only two countries had significantly lower rates. Similarly, only one of the 11 countries that ranked ahead of Canada had a significantly lower rate of neonatal mortality excluding live births below 1000 g, and only six of the 16 countries that ranked ahead of England and Wales had significantly lower rates.

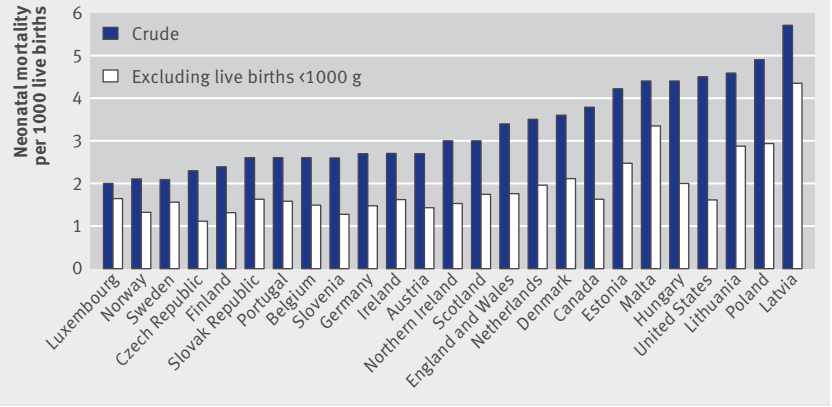
Bias, confounding, and other reasons for caution

Our study cannot provide valid international rankings of countries in terms of health or healthcare services, because factors such as potential variation in true rates of extremely preterm birth, differences in the modality of ascertainment of gestational age, variable registration of births affected by lethal congenital anomalies, and differential labelling of stillbirths versus live births cannot easily be resolved.

Study funding/potential competing interests

The study received no funding.

Differences in pattern of crude neonatal mortality rates and neonatal mortality rates excluding live births <1000 g in 25 industrialised countries



Primary screening for human papillomavirus compared with cytology screening for cervical cancer in European settings: cost effectiveness analysis based on a Dutch microsimulation model

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- Economic evaluation of human papillomavirus vaccination in the United Kingdom (*BMJ* 2008;337:a769)
- Hypersensitivity reactions to human papillomavirus vaccine in Australian schoolgirls: retrospective cohort study (*BMJ* 2008;337:a2642)
- Cost effectiveness analysis of including boys in a human papillomavirus vaccination programme in the United States (*BMJ* 2009;339:b3884)
- Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study (*BMJ* 2008;337:a1754)

STUDY QUESTION When is screening for human papillomavirus (HPV) in Europe more cost effective than and preferable to cytology screening?

SUMMARY ANSWER Primary HPV screening was the preferred primary test in women over the age of 30 in many European scenarios. Primary cytology screening was preferred only when cytology was at low cost and when HPV was highly prevalent and its testing was costly.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Screening for cervical cancer using HPV tests has higher sensitivity but lower specificity than cytology for detecting clinically relevant lesions. Previous cost effectiveness analyses on HPV screening are heterogeneous, partly because key variables differ between countries. Five realistic European scenarios showed that primary HPV screening was often preferable.

Main results

The results were consistent for incremental cost effectiveness thresholds between €20 000 and €50 000 per quality adjusted life year (QALY) gained.

Design

Our base case analyses of HPV screening versus cytology screening investigated the cost effectiveness of more than 1500 screening policies using the microsimulation model MISCAN. The policies varied by type of primary and triage tests, number of screening rounds, screening interval, and age at first screening. We compared these policies for five realistic scenarios differing in key variables: risk of cervical cancer, previous screening, quality associated test characteristics, costs of testing, and prevalence of HPV.

Sources of effectiveness

The costs and effects (in terms of the numbers of life years gained and QALYs gained) of the screening policies were accounted for until all simulated women had died to determine the efficient strategies.

Data sources

The MISCAN-cervix model was validated using Dutch data. All costs were derived from cost studies in the Netherlands. European data came from international databases and studies.

Results of sensitivity analysis

With a high prevalence of HPV primary cytology screening was preferred only if higher costs for HPV screening (total €64; £54; $85) were assumed. In case of low costs for cytology (total €26), primary cytology was preferred, notwithstanding the lower sensitivity and specificity that accompanied the lower costs. These results were independent of the background risk level.

Limitations

Screening strategies were not permitted to switch during a woman's lifetime. Some of the parameters that were not varied in the sensitivity analyses were based on Dutch data. We estimated the prevalence of HPV using the percentage of HPV positive women in randomised controlled trials of cervical cancer screening with HPV testing as the primary test, which may not be representative of real practice. We assumed full attendance at follow-up screenings and referrals for colposcopy. Use of QALYs depends on the reliability of quantification of quality of life aspects of screening and cervical cancer.

Study funding/potential competing interests

IMCMdK, MvB, and JvR were supported by the European Union and the Dutch National Institute for Public Health and the Environment, MA was supported by the European Union and the Belgian Foundation against Cancer, and JD was supported by the European Union; in the previous three years IMCMdK, MvB, TI, PS, and JD have received industry grants, other support, or other payments (details in full version on bmj.com); MA has received a grant from the University of Ghent; and PS has received a grant from the Cancer Research UK programme.

Preferred primary test for different levels of sensitivity of human papillomavirus (HPV) screening (90% *v* 95%), and laboratory costs of HPV test (€21 *v* €33)

	Laboratory costs HPV test €21		Laboratory costs HPV test €33	
Scenarios	**90% sensitive**	**95% sensitive**	**90% sensitive**	**95% sensitive**
Base case (low risk):	HPV	HPV	HPV	HPV
Average risk, high HPV prevalence	HPV	HPV	Cytology	Cytology
Average risk, low sensitivity and specificity of cytology	HPV	HPV	HPV	HPV
Low risk, low specificity of cytology	HPV	HPV	HPV	HPV
High risk, high HPV prevalence	HPV	HPV	Cytology	Cytology
High risk, no past screening, and low sensitivity, specificity, and cost of cytology	Cytology	Cytology	Cytology	Cytology

Results were consistent for incremental cost effectiveness thresholds between €20 000 and €50 000 per QALY gained.
€1.00 (£0.84; $1.31).