RESEARCH

The *BMJ* is an Open Access journal. We set no word limits on *BMJ* research articles, but they are abridged for print. The full text of each *BMJ* research article is freely available on bmj.com

THIS WEEK'S RESEARCH QUESTIONS

A safer NHS; but why?

Between 2004-8 a British charity, The Health Foundation, ran a Safer Patients Initiative (SPI) to test ways of preventing harms from routine hospital care (http://bit.ly/gTYXBO). The initiative's aims and methods were similar to those of the US "Saving 100,000 lives" campaign and, indeed, the US Institute for Healthcare Improvement designed and oversaw both of these programmes.

The first phase of the initiative took place in one hospital in each UK country before being rolled out to a further 20 hospitals in 2006. Amirta Benning and colleagues now report their evaluations of both the first (p 369) and second phases (p 370). As Peter Provonost and colleagues say in a linked editorial, these studies bring mixed news (p 341).

The good news is that safety and quality of care improved in these NHS hospitals over the study period. Along with John Appleby's data briefing on the UK's relatively good health outcomes (doi:10.1136/bmj.d56) and an all-time high in public ratings of the NHS (http://bit.ly/g06eeN) these findings contradict the government's assertion that the NHS needs urgent reform. But Benning and colleagues also found that the improvement could not be attributed to the Safer Patients Initiative: overall, care improved equally in both treatment and comparison hospitals. That's not surprising, say the editorialists, because the interventions were not well enough selected, designed, or piloted, and the programme failed to get enough buy in and leadership from clinicians.

Feedback in CPR

Devices that deliver feedback "may be useful" in helping rescuers give high quality cardiopulmonary resuscitation (CPR), according to the European Resuscitation Council's guidelines, but there's been no clear evidence to support the use of such devices in any particular setting. David Hostler and colleagues did a multicentre, cluster-randomised trial assessing the effectiveness of real-time audiovisual feedback on CPR after out of hospital cardiac arrest in more than 1500 patients (p 371). Clusters of emergency medical service providers in North America were randomised to use the monitor-defibrillator with or without feedback, and the groups switched between the treatment arms throughout the study. Although the results showed improvements in CPR performance when feedback was used, these improvements failed to translate into better return of spontaneous circulation or other clinical outcomes. In an accompanying editorial, Peter Leman considers why this might be so (p 342).

Another recent *BMJ* paper looked at chest compression only CPR—which is increasingly used by lay rescuers—compared with conventional CPR (doi:10.1136/bmj.c7106) Toshio Ogawa and colleagues did an observational study including data from over 40 000 out-of-hospital resuscitation attempts by lay people in Japan. They found that conventional CPR had better outcomes than chest compression only CPR for some patients, such as those with arrests of non-cardiac origin, younger people, and people in whom the start of CPR was delayed.

DR P MARAZZI/SPL

Dodging the white coat effect

Measurements of blood pressure in the clinic are subject to many sources of inaccuracy, including variation in technique and the "white coat effect." Ambulatory and home measurements are more reliable, but are not without their drawbacks, especially since the evidence base for hypertension treatment relies on clinical values. Martin Myers and colleagues did a cluster randomised controlled trial examining a third option: the use of an automated device by patients to measure their own blood pressure in the clinic (p 372). In the intervention group, primary care patients with systolic hypertension sat alone in a quiet room while taking their own measurements. Readings taken with this method were closer to the patients' 24 hour ambulatory blood pressures than were those taken manually in the control group—although the automated method did not completely eliminate the white coat effect. In an editorial (p 343), Jonathan Mant and Richard McManus say that the precise role of this method still needs to be determined, and that the findings highlight the importance of measuring blood pressure properly. A reviewer remarked that they would be happy to see this paper about "the bread and butter of primary care" in a general journal where it could reach its target audience of GPs and practice nurses.

LATEST RESEARCH: For this and other new research articles see www.bmj.com/research

Gerd Gigerenzer and colleagues recently challenged journals to report more absolute risks in the abstracts of research papers (*BMJ* 2010; 341:c4830). That's fair enough for randomised controlled trials, but for many observational studies and meta-analyses absolute results can't always be reported easily or meaningfully in a nice short summary statistic.

Debate in bmj.com's Rapid Responses illustrates this point well. Sven Trelle and colleagues' network meta-analysis on the cardiovascular safety of non-steroidal anti-inflammatory drugs found some risk for all such drugs, with naproxen looking the safest (*BMJ* 2011; 342:c7086). GP Alex Thain responded "it would really help me, today seeing my real patients, to have some idea of the numbers needed to harm. If the cardiovascular risk for my patients rises from 1% to 4% for example, they are at perfect liberty to remember that they therefore have a 96% chance of not having a cardiovascular event" (http://bit.ly/hASD1y).

The authors replied "Measures of absolute risk, including numbers needed to harm or numbers needed to treat, should not be directly pooled in meta-analysis. Rather, NNH and NNT need to be calculated from the rate ratio based on an assumed baseline risk, which will depend on characteristics of a specific population. Event rates in included trials were considerably lower than what is observed in routine clinical settings " (http://bit.ly/h1RWZC). Helpfully, they added a table giving the NNH/NNTs for each drug comparison and for patients at low, medium, or high baseline risk. But they made the point well that you can't always state an absolute risk in a paper's abstract.

Large scale organisational intervention to improve patient safety in four UK hospitals: mixed method evaluation

Amirta Benning,[1] Maisoon Ghaleb,[2 3] Anu Suokas,[4] Mary Dixon-Woods,[5] Jeremy Dawson,[6] Nick Barber,[2] Bryony Dean Franklin,[2 7] Alan Girling,[1] Karla Hemming,[1] Martin Carmalt,[8] Gavin Rudge,[1] Thirumalai Naicker,[1] Ugochi Nwulu,[9] Sopna Choudhury,[1] Richard Lilford[1]

EDITORIAL by Pronovost and colleagues
RESEARCH p 370

[1]School of Health and Population Sciences, University of Birmingham, Edgbaston, West Midlands B15 2TT, UK
[2]Department of Practice and Policy, School of Pharmacy, University of London, London WC1N 1AX
[3]School of Pharmacy, University of Hertfordshire, Hatfield, Hertfordshire AL10 9AB
[4]Arthritis Research UK Pain Centre, Academic Rheumatology, Clinical Sciences Building, City Hospital, Nottingham NG5 1PB
[5]Department of Health Sciences, University of Leicester, Leicester LE1 7RH
[6]Work and Organisational Psychology Group, Aston Business School, Aston University, Aston Triangle, Birmingham B4 7ET
[7]Imperial College Healthcare NHS Trust, St Mary's Hospital, London W2 1NY
[8]Royal Orthopaedic Hospital, Bristol Road South, Northfield, Birmingham B31 2AP
[9]Clinical Investigation Unit, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, Queen Elizabeth Medical Centre, Birmingham B15 2TH
Correspondence to: R J Lilford
r.j.lilford@bham.ac.uk

Cite this as: *BMJ* 2011;342:d195
doi: 10.1136/bmj.d195

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;342:d195

STUDY QUESTION What was the impact of the first phase of a large scale hospital-wide patient safety programme mentored by the Institute of Health Improvement (IHI), the organisation that implemented the American "Saving 100,000 lives campaign"?

SUMMARY ANSWER The quality of the monitoring of sick patients on medical wards improved in hospitals participating in the programme compared with control hospitals, but impacts of the programme on other aspects of care could not be detected.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Quality improvement interventions targeting specific clinical issues (such as reduction in healthcare acquired infection) have shown encouraging results in several studies. Our study suggests that achieving systemic change across whole organisations might be more difficult to demonstrate, at least in relatively short time scales.

Participants and setting

Four intervention and 18 control hospitals in the United Kingdom.

Design, size, and duration

The Health Foundation, an independent charitable foundation dedicated to quality improvement in healthcare, commissioned the Safer Patients Initiative (SPI), a multicomponent programme aimed at transforming organisational approaches to delivering safer care in hospitals. It invested £775 000 (€900 000, $1.2m) in each of the four participating UK hospitals. The programme was designed and mentored by the IHI. Delivered over 18 months (2005-6), the SPI intervened at both the organisational level, by building leadership and expertise in patient safety, and in specific frontline processes.

The Health Foundation commissioned an independent evaluation involving qualitative and quantitative observations at multiple levels in participating hospitals. For the quantitative component, 18 control hospitals were used so that a difference in difference analysis could be undertaken.

Main results and the role of chance

Senior staff mostly understood the SPI and believed in it. There were improvements in monitoring of sick patients across both sets of hospitals, and one aspect of monitoring—observation of the respiratory rate—improved to a greater extent in SPI than in control hospitals. There was also a small improvement in staff perceptions of "organisational climate." There were, however, no further effects of SPI on clinical errors, perceptions of staff or patients, adverse events, or death rates. Qualitative and quantitative observations were convergent; the need to improve monitoring of sick patients resonated strongly with ward staff, but other aspects of the programme had limited impact.

Bias, confounding, and other reasons for caution

This was a non-randomised study, but control and SPI hospitals were similar at baseline. Improvements might have occurred at a level that could not be detected, appeared in clinical areas not captured in the study, or took longer to surface than the timescale allowed by the evaluation.

Generalisability to other populations

Participating hospitals were widely dispersed across the UK, including large and small institutions and both city and small town locations. The results are therefore generalisable across the UK, but SPI might be more effective in countries where there are fewer competing safety initiatives and hence more room for improvement.

SUBSTUDIES IN EVALUATION OF PHASE ONE OF SAFER PATIENTS INITIATIVE (SPI1)

Substudy	Topic	Finding
Interviews with senior staff in SPI hospitals	Perceptions of SPI	Senior staff mostly knowledgeable and enthusiastic about SPI
Staff survey in control and SPI hospitals	Staff morale, culture, and opinion	Small effect in favour of SPI1 hospitals in one of 11 dimensions (organisational climate)
Qualitative study of acute medical wards in SPI hospitals	Impact of SPI at ward level	Little evidence of penetration of SPI into culture and behaviour at medical ward level, except in monitoring of vital signs
Quality of care assessed with review (explicit and holistic) of case notes in acute medical care wards in control and SPI hospitals for patients aged >65 with acute respiratory disease	Quality of care on medical wards	Improvement in monitoring of vital signs in SPI hospitals but not any other measure
Outcomes in control and SPI hospitals	Adverse events in patients aged >65 with acute respiratory disease Hospital mortality in patients aged >65 with acute respiratory disease Patients' satisfaction	No additive effect of SPI detected

Multiple component patient safety intervention in English hospitals: controlled evaluation of second phase

Amirta Benning,[1] Mary Dixon-Woods,[2] Ugochi Nwulu,[3] Maisoon Ghaleb,[4 5] Jeremy Dawson,[6] Nick Barber,[4] Bryony Dean Franklin,[4 7] Alan Girling,[1] Karla Hemming,[1] Martin Carmalt,[8] Gavin Rudge,[1] Thirumalai Naicker,[1] Amit Kotecha,[8] M Clare Derrington,[9] Richard Lilford[1]

EDITORIAL by Pronovost and colleagues
RESEARCH p 369

[1]School of Health and Population Sciences, University of Birmingham, Edgbaston, West Midlands B15 2TT, UK
[2]Department of Health Sciences, University of Leicester, Leicester LE1 7RH
[3]Clinical Investigation Unit, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, Birmingham B15 2TH
[4]Department of Practice and Policy, School of Pharmacy, University of London, London WC1N 1AX
[5]School of Pharmacy, University of Hertfordshire, Hatfield, Hertfordshire AL10 9AB
[6]Work and Organisational Psychology Group, Aston Business School, Aston University, Birmingham B4 7ET
[7]Imperial College Healthcare NHS Trust, St Mary's Hospital, London W2 1NY
[8]Royal Orthopaedic Hospital, Northfield, Birmingham B31 2AP
[9]45 Weston Road, Edith Weston, Rutland LE15 8HQ
Correspondence to: R J Lilford
r.j.lilford@bham.ac.uk

Cite this as: *BMJ* 2011;342:d199
doi: 10.1136/bmj.d199
This is a summary of a paper that was published on bmj.com as *BMJ* 2011;342:d199

STUDY QUESTION Has the NHS become safer for patients and has the second phase of the Safer Patients Initiative (SPI2) had an additional impact on safety?

SUMMARY ANSWER There was a general improvement across all hospitals during the study period, suggesting that care in the NHS has indeed become safer. The SPI hospitals, however, did not improve more than the control hospitals.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS There has been a concerted effort to improve the quality of NHS care over the past decade. Compliance with several standards of safe and effective care was already high at the start of the study. Though marked improvements were found on many other measures of safety over the study period, SPI hospitals did not show more improvement than the control hospitals on the study measures.

Participants and setting
Nine SPI and nine control hospitals (matched on size and urban versus rural setting) in England.

Design, size, and duration
SPI2 was similar to the SPI1 intervention with some minor amendments, but with a reduced allocation of £270 000 (€314 000, $430 000) per hospital. It was rolled out over 20 months (2007-8). This study comprised controlled before and after evaluation with a difference in difference analysis of staff attitudes, error rates, and outcomes in patients. It included medical, perioperative, and intensive care settings, along with hospital-wide observations of infection rates, staff attitudes, and patients' satisfaction.

Main results and the role of chance
Adherence to many standards of safe and effective care (such as perioperative prophylaxis against deep vein thrombosis) was already high at baseline across all hospitals. Where there was room for improvement, marked improvements were found across both sets of hospitals. For example, in a continuation of a trend seen in SPI1, monitoring of vital signs improved, as did handwashing, infection rates, patients' satisfaction, and the quality of medical histories. There were no systematic differences in the magnitudes of improvement across control and SPI hospitals. Although the study was large enough to detect differences over time in the control group, we cannot exclude the possibility of smaller incremental effects in the SPI hospitals.

Bias, confounding, and other reasons for caution
Control and SPI hospitals were similar at baseline, but controls were not selected at random and selection bias is therefore possible. Improvements resulting from SPI might take longer to surface than the timescale allowed by the evaluation. An important constraint on detecting the effect of the programme was the contemporaneous introduction by the Department of Health and other national agencies of programmes similar to the SPI. This could have reduced the ability to detect any effects of the SPI, which might be more easily seen in settings without such national programmes.

Generalisability to other populations
This study evaluated a particular intervention (SPI) in a particular setting (English NHS), and a more complete picture must await studies in other contexts and over a longer time span.

SUBSTUDIES IN EVALUATION OF PHASE TWO OF SAFER PATIENTS INITIATIVE (SPI2)

Substudy	Topic	Finding
Staff survey in control and SPI2 hospitals	Staff morale, culture, and opinion	Measure of organisational climate showed significant difference in rate of change over time, but favoured control hospitals. No other differences between control and SPI2 hospitals
Case note reviews (explicit and implicit) of quality of care in acute medical care	Quality of care of patients aged >65 with acute respiratory disease	Compliance with several standards improved over time; no significant differences between control and SPI2 hospitals
Explicit case note review of quality of perioperative care	Quality of perioperative care in total hip replacement and open colectomy	Practices good at baseline and no significant differences between control and SPI2 hospitals
National observation study of effectiveness of national "cleanyourhands" campaign	Use of hand hygiene consumables	Increase in handwashing materials over time but no significant differences between control and SPI2 hospitals
Outcomes assessed with:		
Holistic case note review	Adverse events in patients aged >65 with acute respiratory disease	No significant differences between control and SPI2 hospitals, but improvements in infection rates and patient satisfaction seen across both groups
Case note review	Hospital mortality in patients aged > 65 with acute respiratory disease	
Routine data from Intensive Care National Audit and Research Centre	ICU mortality	
Routine data from Health Protection survey	Infection rates associated with healthcare	
NHS patient surveys	Patients' satisfaction	

Effect of real-time feedback during cardiopulmonary resuscitation outside hospital: prospective, cluster-randomised trial

David Hostler,[1] Siobhan Everson-Stewart,[2] Thomas D Rea,[3] Ian G Stiell,[4] Clifton W Callaway,[1] Peter J Kudenchuk,[3] Gena K Sears,[2] Scott S Emerson,[2] Graham Nichol,[2 3 5] and the Resuscitation Outcomes Consortium Investigators

EDITORIAL by Leman

[1]University of Pittsburgh, Department of Emergency Medicine, 3600 Forbes Ave, Suite 400A, Pittsburgh PA 15261, USA
[2]University of Washington Clinical Trial Center, Department of Biostatistics, Seattle WA, USA
[3]University of Washington, Department of Medicine, Seattle WA
[4]University of Ottawa, Department of Emergency Medicine, Ottawa ON, Canada
[5]University of Washington-Harborview Center for Prehospital Emergency Care, Seattle WA
Correspondence to: D Hostler
hostlerdp@upmc.edu

Cite this as: *BMJ* 2011;342:d512
doi: 10.1136/bmj.d512

This is the summary of a paper that was published on bmj.com as *BMJ* 2011;342:d512

STUDY QUESTION Does real-time audiovisual feedback during cardiopulmonary resuscitation (CPR) increase the proportion of patients who achieve prehospital return of spontaneous circulation?

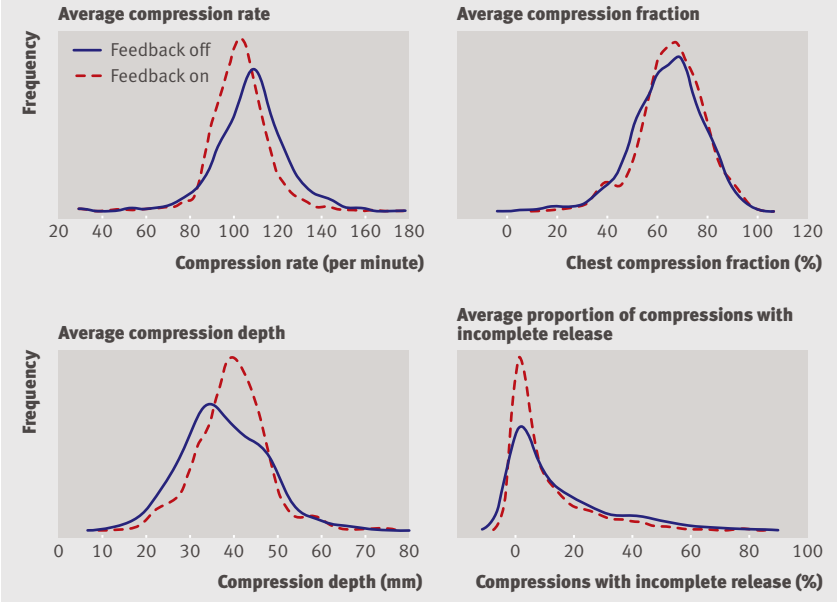
SUMMARY ANSWER Real-time feedback improved CPR performance, but this was not associated with improvements in return of spontaneous circulation or other clinical outcomes.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Real-time feedback has been shown to improve acquisition and retention of CPR skills. This large, prospective study shows that improved CPR performance does not necessarily translate to improved clinical outcomes.

Design

A cluster-randomised trial of real-time audio and visual feedback, provided by the monitor-defibrillator, of cardiopulmonary resuscitation (CPR) performed by emergency medical services. Clusters of the emergency medical service providers were randomised to perform CPR with the feedback ("feedback-on") or without it ("feedback-off"). After a certain period each cluster switched to the opposite treatment arm, and continued to switch periodically for the duration of the study. Providers were not blinded to the intervention.

FREQUENCY DISTRIBUTION OF MEASURES OF CPR PROCESS BY WHETHER REAL-TIME CPR FEEDBACK PROVIDED



Participants and setting

The trial included 1586 people having cardiac arrest outside hospital in whom resuscitation was attempted by emergency medical services from three sites in the Resuscitation Outcomes Consortium in North America: 771 procedures were conducted without feedback and 815 with feedback.

Primary outcome(s)

The primary outcome was prehospital return of spontaneous circulation for feedback-on procedures compared with feedback-off.

Main results and the role of chance

Baseline patient and emergency medical service characteristics did not differ between the two treatment arms. Emergency medical service providers muted audible feedback in 14% of cases during the feedback-on period. Compared with feedback-off, clusters assigned to feedback-on were associated with increased proportion of time in which chest compressions were provided (64% *v* 66%, cluster-adjusted difference 1.9 (95% CI 0.4 to 3.4)), increased compression depth (38 *v* 40 mm, adjusted difference 1.6 (0.5 to 2.7)), and decreased proportion of compressions with incomplete release (15% *v* 10%, adjusted difference −3.4 (−5.2 to −1.5)). However, the proportion of prehospital return of spontaneous circulation did not differ according to feedback status (45% *v* 44%, adjusted difference 0.1 (−4.4 to 4.6)).

Harms

No study related adverse events were reported.

Bias, confounding, and other reasons for caution

Feedback might be expected to have a greater impact in settings where CPR performance is poor. In the current study, measures of CPR in the feedback-off arm were better than reported elsewhere for CPR outside hospital, potentially leaving little opportunity for improvement by real-time feedback.

Generalisability to other populations

The emergency medical service agencies participating in this study may not be typical of agencies across North America. Although diverse in both operational practices and population served, agencies with the resources and commitment required to participate in prehospital clinical trials may deliver a different level of care than those that do not.

Trial registration number

Clinical Trials NCT00539539.

Conventional versus automated measurement of blood pressure in primary care patients with systolic hypertension: randomised parallel design controlled trial

Martin G Myers,[1] Marshall Godwin,[2] Martin Dawes,[3] Alexander Kiss,[4] Sheldon W Tobe,[5] F Curry Grant,[6] Janusz Kaczorowski[7]

EDITORIAL by Mant and McManus

[1]Schulich Heart Centre, Department of Medicine, University of Toronto, Toronto, ON, Canada
[2]Department of Family Medicine, Memorial University of Newfoundland, St John's, NF, Canada
[3]Department of Family Medicine, McGill University, Montreal, QC, Canada
[4]Department of Research Design and Biostatistics, Sunnybrook Health Sciences Centre, Toronto
[5]Department of Medicine, University of Toronto
[6]Stroke Prevention Clinic, Quinte Health Care, Belleville, ON, Canada.
[7]Department of Family Practice, University of British Columbia, Vancouver, Canada

Correspondence to: M Myers, Schulich Heart Centre, Division of Cardiology, Sunnybrook Health Sciences Centre, A-202, 2075 Bayview Avenue, Toronto, ON, Canada M4N 3M5
martin.myers@sunnybrook.ca

Cite this as: *BMJ* 2011;342:d286
doi: 10.1136/bmj.d286

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;342:d286

STUDY QUESTION Can office induced hypertension (white coat response) be reduced by recording blood pressure with an automated device with the patient resting alone?

SUMMARY ANSWER Automated office blood pressure measured with the BpTRU device virtually eliminated the white coat response seen with routine manual office blood pressure measurement, with readings similar to mean awake ambulatory blood pressure, a gold standard for evaluating future cardiovascular risk related to blood pressure status.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS In routine clinical practice, manual office blood pressure is often associated with higher readings of poor quality and accuracy compared with research quality manual, home, or ambulatory blood pressure readings. This increase in office blood pressure can be substantially reduced by using automated office blood pressure measurement, providing the patient is left alone in the examining room, with improved accuracy and quality of readings.

Design

In this multi-site cluster randomised controlled trial, we allocated primary care practices to either ongoing use of manual office blood pressure measurement (control group) or automated office blood pressure measurement using the BpTRU device (intervention group). We noted the last routine manual office blood pressure before enrolment from each patient's medical record. We compared office blood pressure readings before and after enrolment in the two groups and also compared readings with the mean awake ambulatory blood pressure.

MEAN (SD) BP TAKEN IN PHYSICIANS' OFFICE BEFORE AND AFTER ENROLMENT INTO STUDY AND BASELINE MEAN AWAKE AMBULATORY BP RECORDED BETWEEN TWO OFFICE VISITS FOR PATIENTS RANDOMISED TO INTERVENTION AND CONTROL GROUPS, WITH ESTIMATED MEAN DIFFERENCES (95% CI) BETWEEN BP READINGS

Measurement	Automated office BP (intervention) group (n=299)	Conventional manual office BP (control) group (n=249)
Last routine manual office BP (mm Hg)	149.5 (10.8)/81.4 (8.3)	149.9 (10.7)/81.8 (8.5)
Office BP (mm Hg) after enrolment	135.6 (17.3)/77.7 (10.9)	141.4 (14.6)/80.2 (9.5)
Difference from last routine office BP (mm Hg)	−13.9 (−11.8 to −16.1)***/ −3.7 (−2.5 to −4.8)***	−8.5 (−6.5 to −10.4)***/ −1.6 (−0.4 to −2.8)**
Awake ambulatory BP (mm Hg)	133.2 (12.4)/74.4 (9.8)	135.0 (13.1)/75.9 (10.0)
Difference from last routine office BP (mm Hg)	−16.3 (−14.5 to −18.1)***/ −7.0 (−5.8 to 8.1)***	−14.9 (−12.9 to −17.0)***/ −5.9 (−4.6 to 7.2)***
Difference from post-enrolment office BP (mm Hg)	−2.3 (−0.31 to −4.3)*/ −3.3 (−2.2 to −4.4)***	−6.5 (−4.3 to −8.6)***/ −4.3 (−2.9 to 5.8)***

BP=blood pressure.
*P=0.02. **P=0.01. ***P<0.001.

Participants and setting

We recruited 555 patients with systolic hypertension and no serious comorbidities under the care of 88 primary care physicians in 67 primary care practices in eastern Canada.

Primary outcome(s)

The primary outcome was difference in systolic blood pressure (mm Hg) between awake ambulatory blood pressure minus automated office blood pressure and awake ambulatory blood pressure minus manual office blood pressure.

Main results and the role of chance

Routine manual office blood pressure before enrolment (149.5 (SD10.8)/81.4 (8.3)) was higher (P<0.001) than automated office blood pressure (135.6 (17.3)/77.7 (10.9)). On the first study visit after enrolment, the estimated mean difference for the intervention group between the awake ambulatory systolic/diastolic blood pressure and automated office blood pressure (−2.3 (95% confidence interval −0.31 to −4.3)/−3.3 (−2.7 to −4.4)) was less (P=0.006/P=0.26) than the difference in the control group between the awake ambulatory blood pressure and the manual office blood pressure (−6.5 (−4.3 to −8.6)/−4.3 (−2.9 to −5.8)). Systolic/diastolic automated office blood pressure showed a stronger (P<0.001) within group correlation (r=0.34/r=0.56) with awake ambulatory blood pressure. Digit preference with readings ending in zero was substantially reduced by using automated office blood pressure.

Harms

No adverse events related to measurement of blood pressure occurred during the trial.

Bias, confounding, and other reasons for caution

Participation of the patients in a research study seemed to affect the manual office blood pressure in the control group. Blood pressure was lower after enrolment without the actual readings being more accurate.

Generalisability to other populations

The introduction of automated office blood pressure into routine clinical practice improved the quality and accuracy of blood pressure measurement and reduced the white coat response. This should be generalisable to most other hypertensive patients.

Study funding/potential competing interests

The Heart and Stroke Foundation of Ontario supported this study.

Trial registration number

Clinical trials NCT 00214053.

Effect of training traditional birth attendants on neonatal mortality (Lufwanyama Neonatal Survival Project): randomised controlled study

Christopher J Gill,[1] Grace Phiri-Mazala,[2] Nicholas G Guerina,[13] Joshua Kasimba,[27] Charity Mulenga,[2] William B MacLeod,[14] Nelson Waitolo,[4] Anna B Knapp,[1] Mark Mirochnick,[5] Arthur Mazimba,[7] Matthew P Fox,[18] Lora Sabin,[14] Philip Seidenberg,[17] Jonathon L Simon,[14] Davidson H Hamer[146]

[1]Center for Global Health and Development, Boston University, Boston, MA, USA
[2]Lufwanyama District Health Management Team, Kalulushi, Zambia
[3]Department of Public Health and Community Medicine. Tufts University School of Medicine, Boston, Massachusetts, USA, and Department of Paediatrics, Women and Infants Hospital, Providence, Rhode Island, USA
[4]Department of International Health, Boston University School of Public Health, Boston, MA, USA
[5]Department of Pediatrics, Boston University School of Medicine, Boston, MA, USA
[6]Section of Infectious Diseases, Department of Medicine, Boston University School of Medicine
[7]Center for International Health and Development Zambia (CIHDZ), Lusaka, Zambia
[8]Department of Epidemiology, Boston University School of Public Health

Correspondence to: C J Gill
cgill@bu.edu

Cite this as: *BMJ* 2011;342:d346
doi: 10.1136/bmj.d346

This is a summary of a paper that was published on bmj.com as *BMJ* 2011;342:d346

STUDY QUESTION Can neonatal mortality be reduced in a low resource country setting by training and equipping traditional birth attendants to carry out neonatal resuscitation and to administer antibiotics coupled with facilitated referral to the nearest health facility?

SUMMARY ANSWER Mortality among liveborn infants delivered by intervention birth attendants was significantly reduced by about half by day 28 after birth, chiefly owing to the prevention of deaths from birth asphyxia.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Although neonatal resuscitation is known to be effective in the developed world and is a universal part of immediate postpartum care, this study provides strong evidence that neonatal resuscitation is effective in a low resource setting in the hands of community health workers.

Design

Unblinded, cluster randomised and controlled effectiveness trial. Zambian traditional birth attendants were randomly allocated to receive intervention training (neonatal resuscitation and provision of antibiotics coupled with facilitated referral) or to continue with their existing standard of care (clean delivery practices). Results were statistically adjusted for the effect of clustering.

Participants and setting

Mothers and their newborns (3559 infants delivered, regardless of vital status) and traditional birth attendants (n=127) living in Lufwanyama, Zambia.

Primary outcome(s)

All cause mortality by day 28 after birth among liveborn infants delivered by study birth attendants.

Main results and the role of chance

From 3497 deliveries with reliable information, mortality at day 28 after birth was 45% lower among liveborn infants delivered by intervention birth attendants (rate ratio 0.55, 95% confidence interval 0.33 to 0.90) compared with control birth attendants, for an absolute risk reduction of 17.9 deaths per 1000 live births (95% confidence interval 4.1 to 31.8). Overall, one death was avoided for every 56 births attended by an intervention birth attendant. The greatest mortality reductions were in the first 24 hours of life: 7.8 deaths per 1000 live births for infants delivered by intervention birth attendants compared with 19.9 per 1000 live births for infants delivered by control birth attendants (rate ratio 0.40, 95% confidence interval 0.19 to 0.83). Deaths due to birth asphyxia were reduced by 63% among infants delivered by intervention birth attendants (0.37, 0.17 to 0.81) and by 81% within the first two days after birth (0.19, 0.07 to 0.52). Stillbirths and deaths from serious infection occurred at similar rates in both groups.

Harms

No harms were identified.

Bias, confounding, and other reasons for caution

Adjusting for potential confounders, and reanalysing missing participants as dead had minimal effect on study conclusions. The open label design allowed for the possibility that control birth attendants might learn skills from the intervention attendants, but this would bias conclusions towards the null.

Generalisability to other populations

Our findings are of particular relevance to populations in low resource settings with limited access to healthcare and who rely on obstetric care from community health workers, such as traditional birth attendants.

Study funding/potential competing interests

This study was supported by a cooperative agreement from the United States Agency for International Development, and also by the National Institutes of Health. We have no competing interests.

Trial registration number

Clinicaltrials.gov NCT00518856.

MORTALITY AMONG INFANTS DELIVERED BY INTERVENTION OR CONTROL TRADITIONAL BIRTH ATTENDANTS

	Deaths per 1000 infants delivered			
End point	Intervention group (60 clusters)	Control group (67 clusters)	Total	Cluster adjusted rate ratios (95% CI)
Stillbirths only*	19.4 (38/1961)	18.2 (28/1536)	18.9 (66/3497)	1.07 (0.64 to 1.77)
All cause mortality				
Excluding stillbirths:				
Day 28†	22.8 (43/1889)	40.2 (59/1466)	30.4 (102/3355)	0.55 (0.33 to 0.90)
Week 1†	18.2 (35/1923)	30.5 (46/1508)	23.6 (81/3431)	0.56 (0.31 to 1.01)
Weeks 2-4‡	4.3 (8/1854)	9.2 (13/1420)	6.4 (21/3274)	0.47 (0.20 to 1.11)
Including stillbirths:				
Day 28§	42.0 (81/1927)	58.2 (87/1494)	49.1 (168/3421)	0.72 (0.51 to 1.00)

*Denominator is all births.
†Denominator is all live births.
‡Denominator is all live births, minus week 1 deaths, excluding loss to follow-up during weeks 1-4.
§Denominator is all births, excluding loss to follow-up during weeks 1-4.